United States Court of Appeals for the Federal Circuit

Nos. 2015-1049, -1050
NUVASIVE, INC.,
Appellant,
v.
WARSAW ORTHOPEDIC, INC.,
Cross-Appellant.

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in No. IPR2013-00206

No. 2015-1058
WARSAW ORTHOPEDIC, INC.,
Appellant,
v.
NUVASIVE, INC.
Appellee.

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in No. IPR2013-00208

WARSAW ORTHOPEDIC, INC.'S OPENING AND RESPONSE BRIEF

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May 29, 2015

U.S. Patent No. 8,251,997 B2, Claim 1 (A112-13):

1. A method comprising: making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end; positioning said third surgical instrument such that said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies of the two adjacent vertebrae;

and inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, a non-bone interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

CERTIFICATE OF INTEREST

Counsel for Warsaw Orthopedic, Inc. certify the following:

1. The full name of every party represented by us is: Warsaw Orthopedic, Inc.

2. The name of the real party in interest is: Warsaw Orthopedic, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are: Medtronic plc wholly owns and is the ultimate parent of Warsaw Orthopedic, Inc. Medtronic plc is a publicly traded corporation. No other publicly traded corporation owns 10% or more of the stock of Medtronic plc.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this Court are:

Kirkland & Ellis LLP: Luke L. Dauchot, Nimalka R. Wickramasekera, Steven A. Papazian, John C. O'Quinn, and William H. Burgess

Martin & Ferraro, LLP: Thomas H. Martin and Wesley C. Meinerding

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STATEMENT OF RELATED CASES

No other appeal in or from the same *inter partes* review proceedings at the Patent Trial and Appeal Board ("PTAB" or "Board") was previously before this Court or any other appellate court.

These appeals may affect a pending district court case where Warsaw has asserted the same U.S. Patent No. 8,251,997 B2 against NuVasive. In *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, Case No. 3:12-cv-02738-CAB (MDD) (S.D. Cal.), the claims and counterclaims related to the '997 patent were stayed pending the *inter partes* review proceedings that are the subject of these appeals.

In *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, Nos. 13-1576, -1577, 778 F.3d 1365 (Fed. Cir. Mar. 2, 2015) (per Dyk, J., joined by Lourie and Reyna, JJ.), Warsaw asserted U.S. Patent No. 5,960,973 (A865-82) against NuVasive. The '973 and '997 patents share a common parent application. A866; A81.

JURISDICTIONAL STATEMENT

The Board had jurisdiction over both *inter partes* review proceedings under 35 U.S.C. § 311. The Board issued final written decisions in both proceedings on July 10, 2014, A1-37; A45-80, and denied NuVasive's rehearing request in IPR2013-00206 on August 28, 2014. A38-44.

NuVasive appealed on August 29, 2014; Warsaw appealed on September 9, 2014. All appeals were timely under 35 U.S.C. § 142 and 37 C.F.R. § 90.3(a)(1). This Court has jurisdiction under 35 U.S.C. §§ 141, 319 and 28 U.S.C. § 1295(a)(4)(A).

PRELIMINARY STATEMENT

In the 1990s, Dr. Gary Michelson revolutionized spinal implant fusion surgery with his invention of implants specifically designed for insertion between two vertebrae from the side of a patient's spine (as opposed to the front or the back), and methods and instruments for inserting such implants. Before Dr. Michelson's invention, lateral (from the side) spinal surgery of any kind was rare, and lateral spinal implant fusion procedures simply did not exist. By contrast, procedures approaching from the front or back of the spine were well-developed and accepted, and there was no perceived advantage to changing them; indeed, Dr. Michelson himself contributed to the prior art by inventing implants, methods and instruments designed for those time-tested approaches. Nonetheless, Dr. Michelson had the insight to recognize the advantages that could be obtained by performing spinal implant fusion surgery from the side *and* to also realize that implants could be designed differently—oversized—when they are used in such surgeries. Dr. Michelson was honored for his discoveries: Among other things, he was inducted into National Inventors Hall of Fame, and awarded U.S. Patent No. 8,251,997 ("the '997 patent"), which describes and claims surgical methods using Dr.

Michelson's specially-designed implants.

NuVasive, however, contends that the '997 patent claims are all obvious in light of various combinations of prior art. In jigsaw-puzzle fashion, NuVasive scours the prior art to assemble combinations of unrelated references that—together—it contends have all of the claimed elements. NuVasive borrows from one reference to show lateral-approach limitations, another to show the required surgical instrument limitations, and yet others to purportedly show the claimed implant limitations. But, in so doing, NuVasive does exactly what this Court warns against: It starts with the invention in hand and, with the benefit of hindsight, works backwards along the path the inventor took. NuVasive's obviousness analysis consists of little more than the kind of anticipation-by-multiple-references reasoning that this Court's precedents reject. Indeed, NuVasive identifies no motive or reason for a skilled artisan to come up with the claimed methods in the first place; rather, its arguments boil down to *ipse dixit*.

The Patent Trial and Appeal Board ("PTAB" or "Board") properly rejected NuVasive's arguments as to claims 9-16 and 24-30, but wrongly accepted them as to claims 1-8 and 17-23. For the first set of claims, the

Board rightly found that Dr. Michelson's own prior art patent neither disclosed nor even suggested the oversized implant required by the claims. Far from being the product of a "rigid" analysis, the Board's conclusion is compelled by the facts and evidence. NuVasive had no evidence Dr. Michelson's prior art patent taught to make implants with *any* of the dimensions required by the claims (quite the opposite), much less gave any reason to modify that implant for side—as opposed to front or back—use in the claimed surgical methods. Recognizing as much, on appeal, NuVasive seeks to overturn the Board's decision upholding claims 9-16 and 24-30, by advancing arguments it did not make below and that are without merit.

With respect to claims 1-8 and 17-23, the Board erred in accepting NuVasive's arguments and finding those unpatentable. The Board fundamentally misread the Brantigan reference that NuVasive argues discloses the oversized implant required by these claims. And it fundamentally misunderstood the patent holder's arguments about basic anatomical limitations, which show that the implant disclosed by Brantigan cannot possibly be used in the claimed methods. Nor does the Brantigan reference—or any other reference before the Board—remotely suggest the substantial modifications that would have to be made to

potentially permit its implants to be inserted from the side using the claimed methods. Instead, like NuVasive, the Board started from the premise that a skilled artisan would be motivated to implant Brantigan from the side and simply assumed away the need to find any motivation to modify in the first place. That is not a proper obviousness analysis. The ruling that claims 1-8 and 17-23 are unpatentable should be reversed. In all other respects the Board should be affirmed.

STATEMENT OF THE ISSUES

1. Whether the Board's ruling that NuVasive did not demonstrate the unpatentability of claims 9-16, and 24-30 should be affirmed, where the Board applied the proper legal standard, and where NuVasive's appeal raises meritless disputes over the Board's reading of the prior art and the weight the Board gave NuVasive's expert testimony, and faults the Board for not invalidating claims *sua sponte* by constructing arguments NuVasive never made.

2. Whether NuVasive's challenges to the Board's decision not to institute on "redundant" grounds of invalidity for claims 9-16 and 24-30 are waived and meritless—whether framed as appeal arguments or as a *mandamus* petition.

3. Whether the Board's ruling that claims 1-8 and 17-23 are obvious should be reversed where (a) the Brantigan reference does not disclose the limitations for the claimed implant in the '997 patent and (b) the Board engaged in hindsight reasoning by combining prior art references and identified no facts demonstrating any *ex ante* reason to combine.

4. Whether the Board's ruling that claims 17-23 should be reversed when it relies on a clearly erroneous reading of the Jacobson reference.

STATEMENT OF THE CASE

These appeals arise out of two *inter partes* review proceedings. Warsaw's '997 patent has four independent claims: Nos. 1, 9, 17, and 24. NuVasive challenged the validity of claims 1-8 in IPR2013-00208, and claims 9-30 in IPR2013-00206. A4934; A243. Both proceedings were briefed on the same schedule, argued together, and decided by the same PTAB panel.

NuVasive appeals the ruling in IPR2013-00206 that claims 9 and 24 and their respective dependent claims were *not* shown to be unpatentable.

Warsaw appeals the rulings in IPR2013-00206 and-00208 that claims 1 and 17 and their respective dependent claims are unpatentable.

I. Background

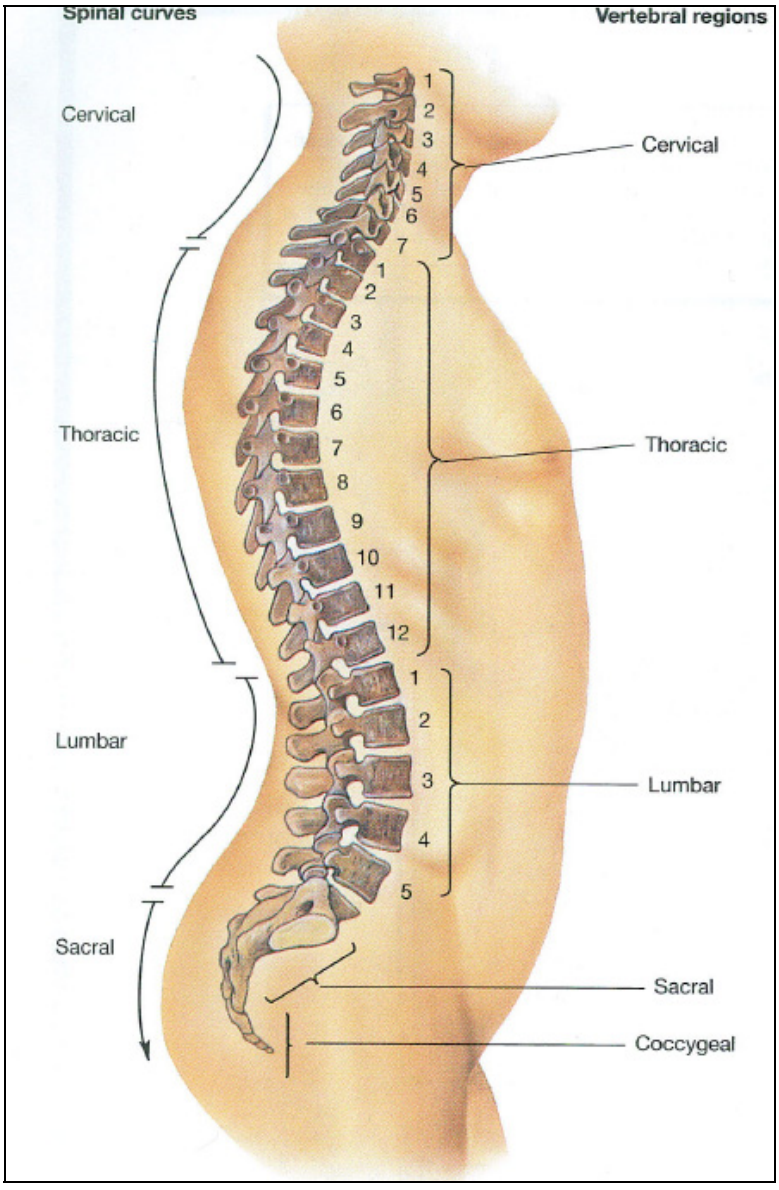
Warsaw's '997 patent is part of a family of patents on Dr. Michelson's inventions concerning spinal surgery. Spinal surgery is a risky endeavor. The spine supports the upper body, surrounds the spinal cord, and sits directly behind the largest artery and vein in the body. If the surgeon, instruments, or implants damage the spinal cord or major blood vessels, the consequences are often paralysis or death. Prior art focused on inserting implants from the front or from the back of the patient, and taught design constraints on the size and structure of spinal implants to avoid contact with the spinal cord and major blood vessels.

The '997 patent overcomes those design constraints and hazards in the prior art by disclosing methods, instrumentation, and specially-designed implants for approaching the spine and inserting implants from the side—as opposed to the front or the back. Such an approach, Dr. Michelson discovered, allows spinal implants to be made "oversized" in a way that leads to better results from the surgery while avoiding the

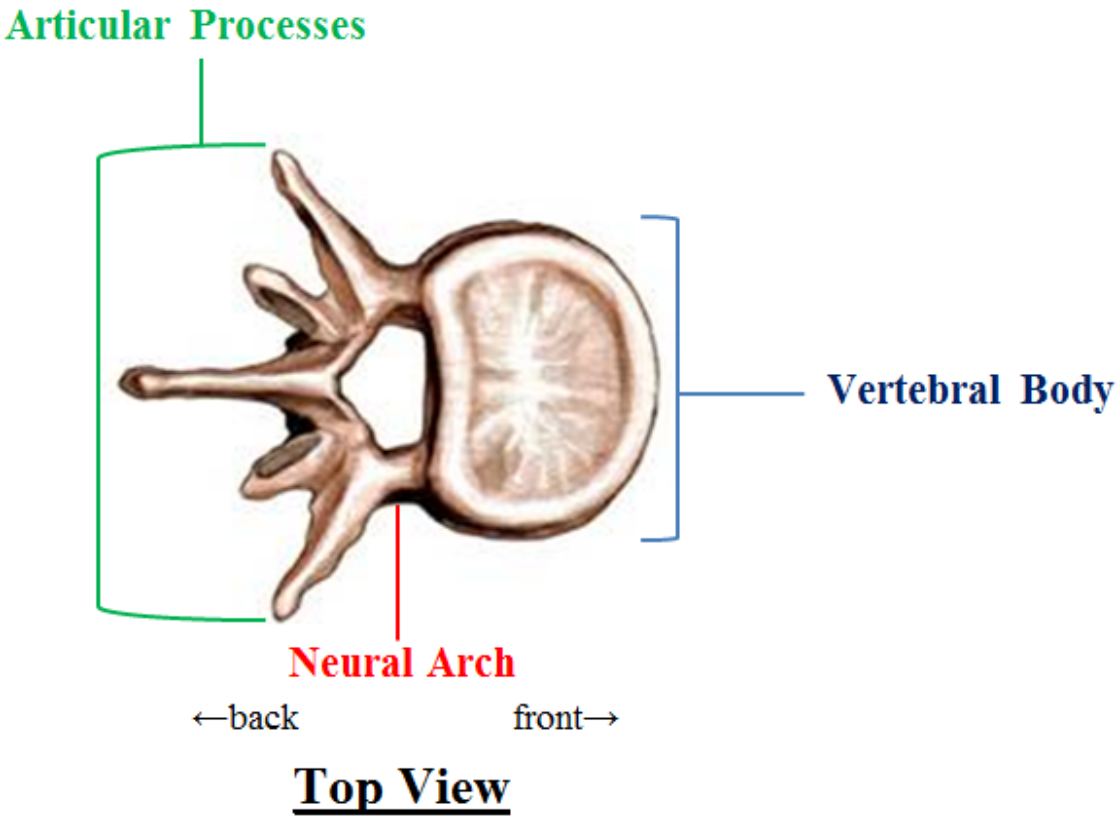
dangers in the prior art. Much of the dispute concerns the implants recited in the claims.

A. Spine Anatomy

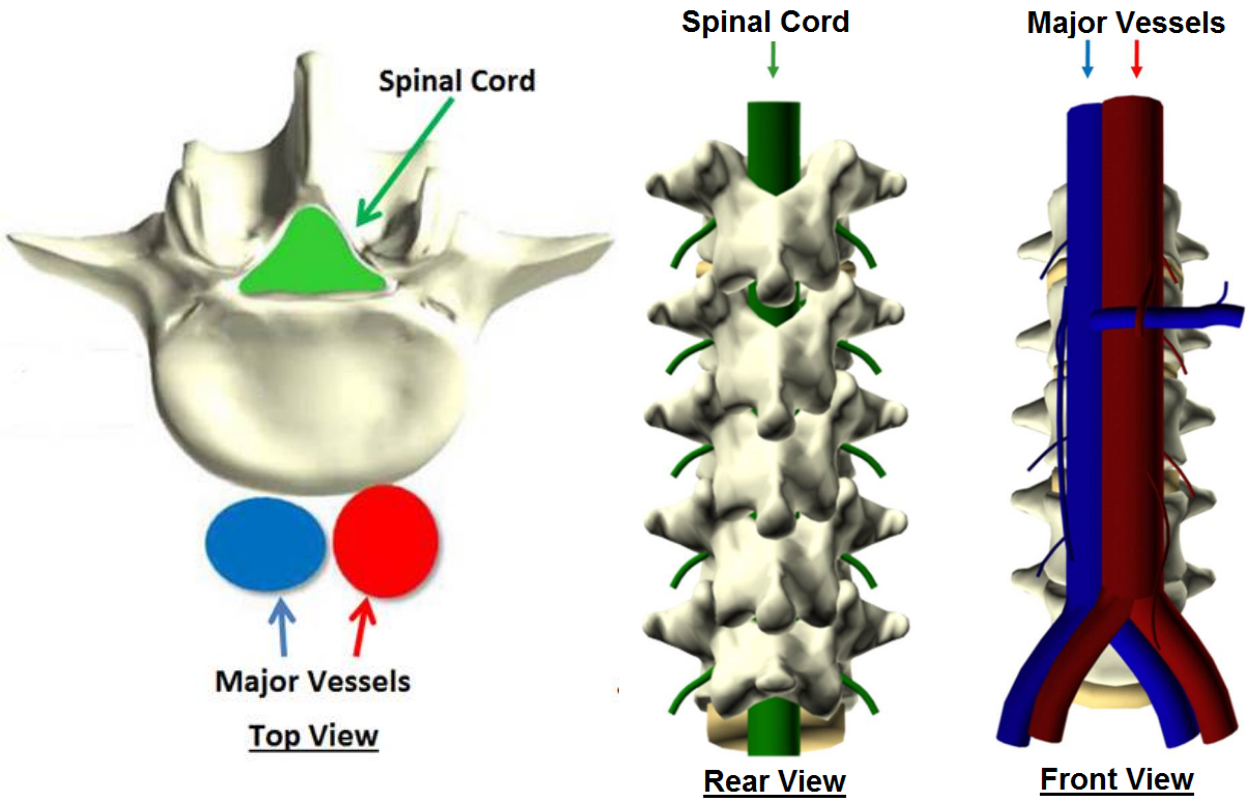
The 24 vertebrae in the human spine are in three regions: seven cervical (neck), twelve thoracic (chest), and five lumbar (lower) vertebrae. A1239 ¶27.



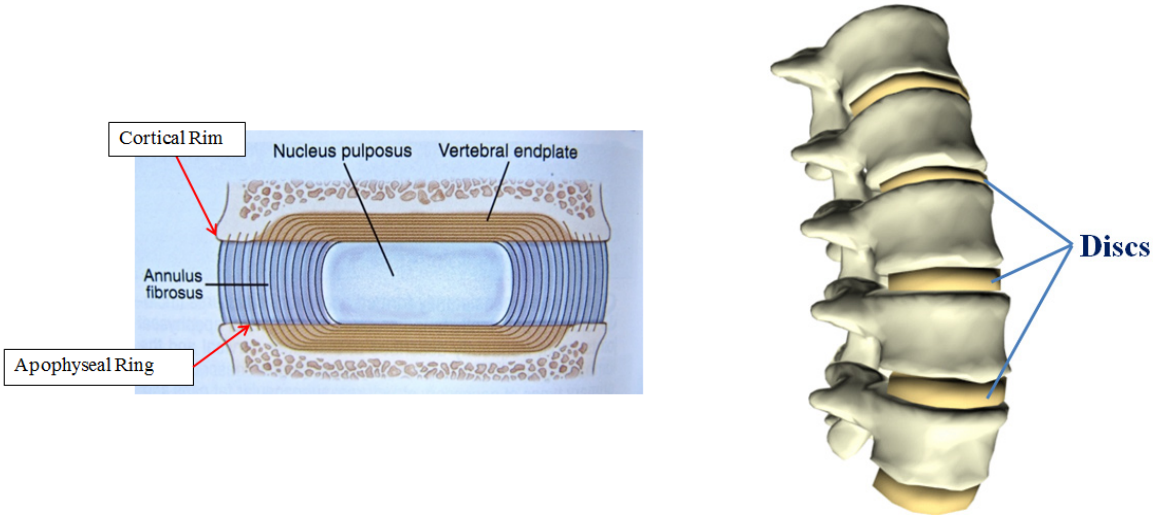
As shown below, each vertebra has three basic parts: a body, a neural arch, and articular processes. A1239 ¶28.



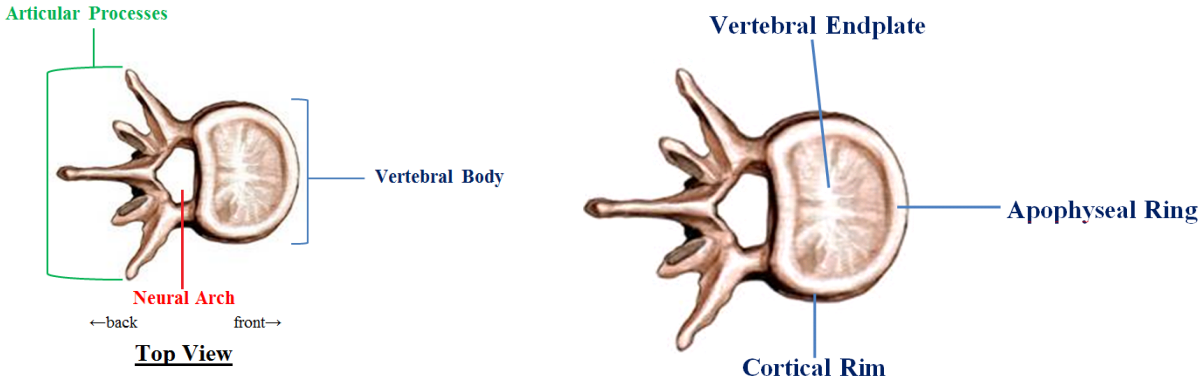
The spinal cord and nerves, encased in a "dural sac," run along the length of the spine, through the opening in the above picture between the neural arch and body of each vertebra. A1238 ¶26. The articular processes protect the spinal cord and attach to muscles and ligaments. The aorta and vena cava (largest artery and vein in the body—also called "great" or "major" vessels) drape the front of the spine. A1238 ¶26, A1308 ¶113, A1313 ¶118.



Between the vertebrae are discs. Discs have soft spongy centers ("nucleus pulposus" below), and tough outer rings of ligament tissue ("annulus fibrosus"). A1239-A1240 ¶¶28-29. Discs absorb shock and maintain spacing between the vertebrae. A1239 ¶28.



The surface of the vertebral body (below-right) has three components. The "endplate" is the center, and contains blood vessels. A1240-41 ¶¶28-29. The apophyseal ring (tracing the circumference of a vertebral body) and the cortical rim (the edge of the vertebral body) are made of harder, denser bone than the endplate, and do not contain blood vessels. *Id.* The spongy "nucleus pulposus" portion of the disc rests on the vertebral endplates, between the vertebrae. *Id.*



B. Spinal Fusion Surgery

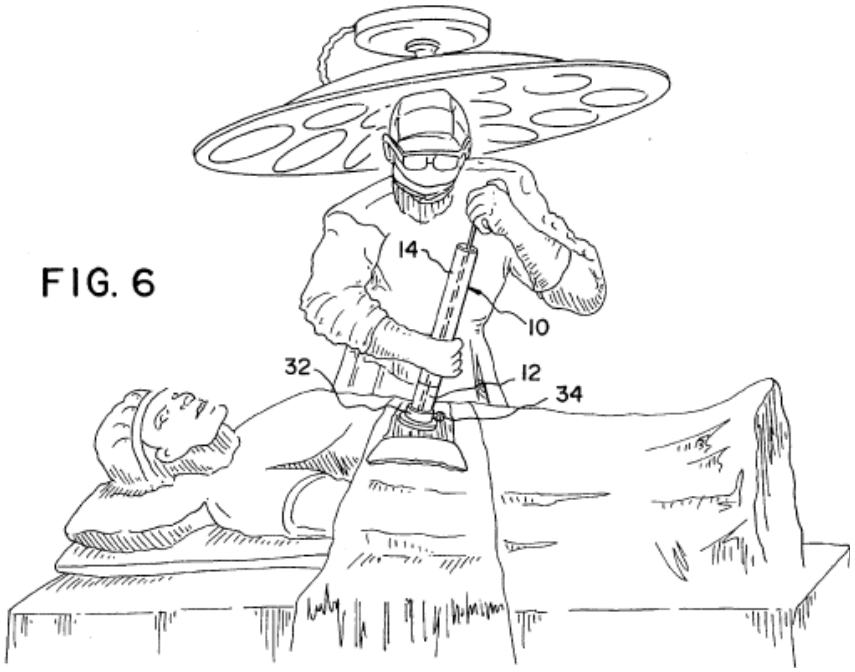
"Spinal fusion" procedures bridge or fuse adjacent vertebrae together to address problems such as a degenerated disc. A1242 ¶30. By fusing two vertebrae together and immobilizing them, spinal fusion alleviates pain caused by motion, stabilizes the spine, and preserves normal spinal curvature. *Id.* Procedures vary in several ways, including the part of the vertebrae to be fused and means of fusing the vertebrae. The '997 patent concerns fusion of vertebral bodies using an implant. The disc is removed

and replaced with an implant, and the vertebrae on either side are fused together and fused to the implant. A growth agent can promote formation of new bone through and around the implant. A1242-43 ¶31.

C. Prior Art

1. Prior Art Surgical Procedures

As this Court noted in a recent appeal involving a related patent, before Dr. Michelson's invention, "implants … were inserted either anteriorly or posteriorly, *i.e.*, from the front or back, rather than the side." *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 778 F.3d 1365, 1370 (Fed. Cir. 2015); *see also* A102-03(2:16–3:17); A1245 ¶36. The McAfee prior art patent illustrates an approach from the front and discloses transparent instruments to give a better view of the surgical site (A540):



Approaching from the front, however, involved tradeoffs. Advantages included avoiding the spinal cord and allowing direct access to the disc—which permitted the use of a single, wider, implant than approaching from the back. A1249-50 ¶44. Drawbacks were the dangerous proximity to the major blood vessels and the need to move or avoid internal organs. When approaching the spine from the front, the vena cava and aorta needed to be moved out of the way. A3226:4-24. That was a delicate and dangerous procedure that could often only be done once because moving those blood vessels caused scarring. *Id.*; A3269:7-11; *see also* A102(2:53)-103(3:17).

Approaching from the back likewise involved tradeoffs—the benefit was a short surgical path that did not require manipulating major blood vessels, but the drawback was the dangerous proximity to the spinal cord and limited space to operate. A1249-50 ¶44.

Some prior art taught approaching the spine from an oblique angle ("anterolateral" or "posterolateral"). A1245 ¶36. But, implants inserted at an angle had to be even smaller than implants inserted from the front or back because of other obstructions, such as articular processes and nerve branches. A102(2:49-52); A1246 ¶39.

Although prior art included the concept of approaching the spine from the side (laterally) for other kinds of surgeries, approaching laterally with an implant for interbody surgery posed different challenges. Approaching the spine from the side required a longer surgical path than the front or the back, A1249-50 ¶44. The bowel often sits between the skin and the spine, obstructing the surgical path. Puncturing the bowel can be harmful or fatal to the patient. A1278-79. In the lumbar region, the surgical path is also obstructed by the psoas—a long, nerve-dense, muscle. A1249; NuVasive Opening Br. 4.

The prior art Jacobson patent generally discusses approaching the spine from the side to cut out damaged disc material. *See, e.g.*, A477 (Abstract); A487(5:1)-A488(8:45). Jacobson discloses percutaneous needle-puncture surgery. A477 (Abstract); A487(5:1)-A488(8:45) Jacobson mentions "fusion" once in passing, A487(6:13) does not discuss implants, and does not discuss or suggest using its needle-puncture processes to insert a large structural spinal implant.

Importantly, prior art spinal implants had different surface characteristics depending on their mode of insertion. The leading end was typically tapered (e.g., a "bullet nose") to facilitate insertion, A3280, and

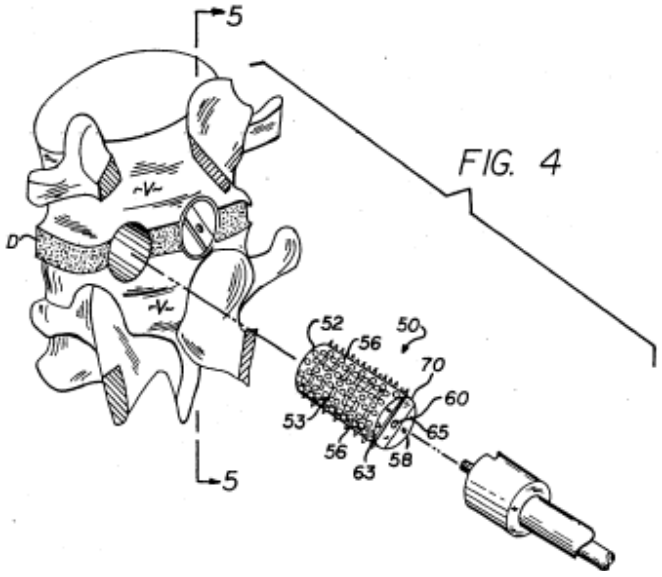
the trailing end was designed to engage surgical instruments. A3280-81. Further, the top and bottom surfaces were typically ridged like barbs on an arrowhead to facilitate insertion and prevent the implant from slipping back out. A3281. In 1994, before Dr. Michelson's invention, lateral spinal surgery of any kind was rare, A1248 ¶43, and *intervertebral implants designed for lateral insertion did not exist*. A1250 ¶45.

2. Prior Art Spinal Implants: Michelson '247 and Brantigan

The size and structure of prior art implants reflected the foregoing considerations. Spinal implants were shorter than the depth of the disc space, to avoid contact with the spinal cord, vena cava, and aorta, to take advantage of contact with the vertebral endplate, and to preserve the tough outer disc tissue for added stability. A103(3:23-26); A1246-47 ¶40. Even as the prior art evolved, it consistently taught placement of the implants *within* the apophyseal ring area of the vertebrae. A1273-74 ¶70, A1307-08 ¶112; A533(10:31-36).

Two references—the Michelson '247 patent (U.S. No. 5,015,247, A522-36) and the Brantigan patent (U.S. No. 5,192,327, A507-16)—relied on by NuVasive—disclose implants reflecting those teachings.

Michelson '247 is an earlier patent by the same Dr. Michelson who invented the '997 patent. In Michelson '247, a hole is drilled into the back of the patient's spine, and a threaded, cylindrical implant is screwed into the hole. A530(3:64-4:4); A533(9:7-10:30). For stability and to avoid the "rocking" that one cylindrical implant might cause, Michelson '247 taught to insert two implants and seat them side-by-side ("bilaterally"). A531(5:3-6); *see also* A533(10:53-56); A530(4:44-51).



To avoid the spinal cord and major vessels, Michelson '247 teaches that the implants should be "recessed into the vertebral bodies," so that they cannot protrude. A533(10:31-36); A1313 ¶118; A530(3:28-38, 3:55-61). Figure 32 of the '997 patent illustrates that prior-art teaching of recessing implants. A100; A111(20:42-54).

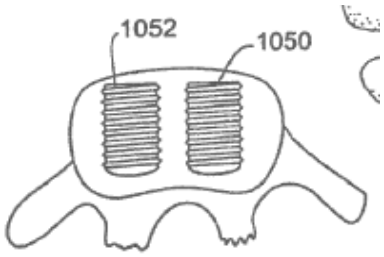


FIG. 32

The Brantigan patent discloses implants that are generally oval-shaped and have teeth on the upper and lower surfaces, A511-12(2:67-3:2); A511(1:59-61), shown below (A508). Brantigan improves on prior art that required "cutting grooves or channels in the vertebrae." A511(1:44-46). Instead of drilling or cutting to make space for the implant, the Brantigan patent discloses implants "generally shaped and sized to conform with the disc space between adjoining vertebrae." A512(4:5-8).

FIG. 1

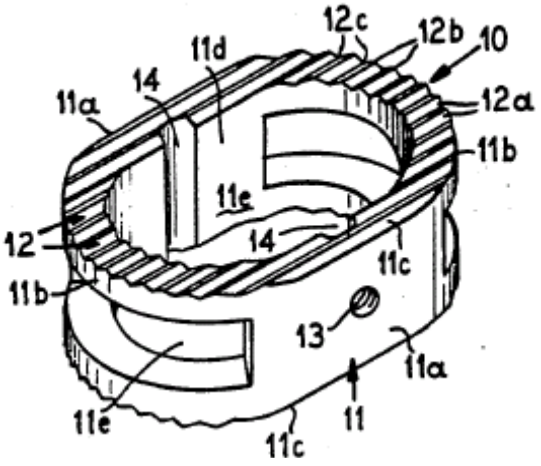
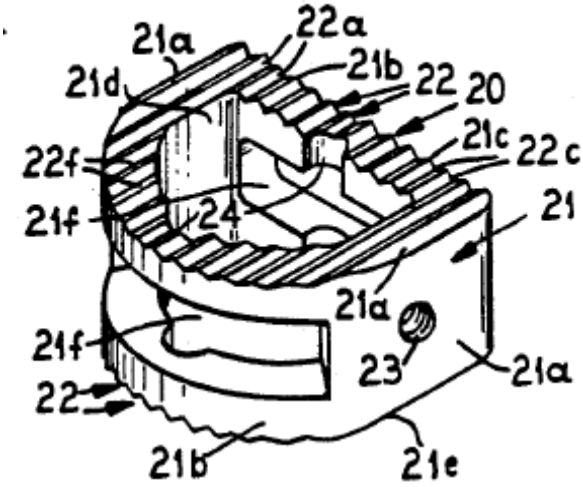
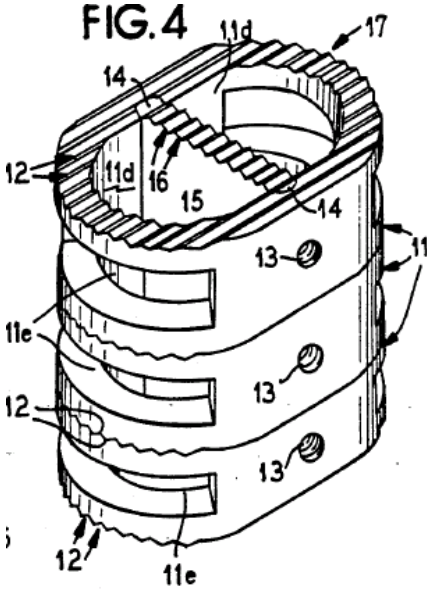
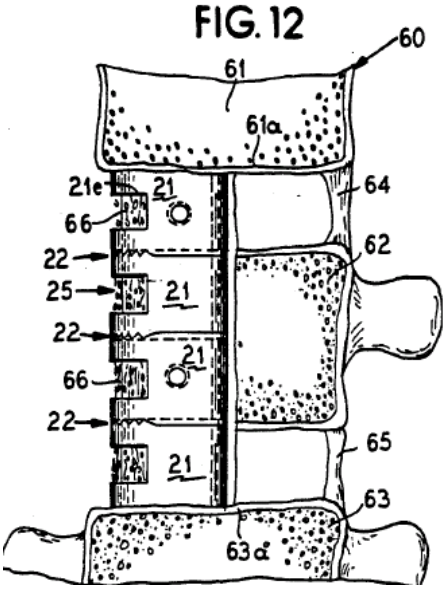


FIG. 2

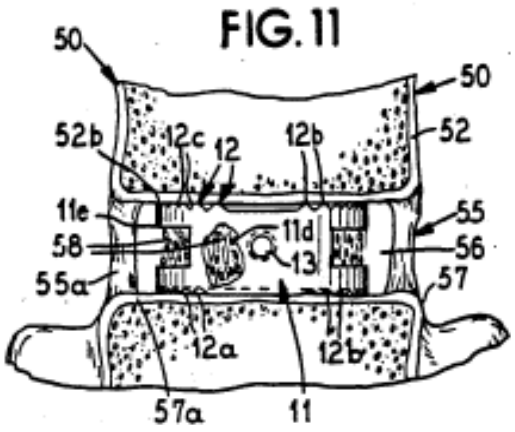


Further, the teeth on the upper and lower surfaces allow multiple implants to be stacked to reach a desired height, as shown in figures 4 and 12 (A508, A510):





The teeth serve two further purposes: anchoring the implant into the vertebrae and facilitating bone ingrowth. A507 (abstract); A511-12(2:67-3:2); *see also* A511(1:13-18, 1:51-54); A512(4:5-8); A513(5:23-24, 6:11-14, 6:23-29); A3139(1495:7-18); A1455-56(1794:24-1795:4); A1273 ¶69. For those purposes, the Brantigan patent repeatedly states, the implants must sit *on the endplate* portion of the vertebrae—within the apophyseal ring—and cannot span more broadly across the full width of the vertebrae. Figure 11 illustrates that teaching (A510):



Claim 1 likewise recites implants that "conform[] in shape and size with hard *end plates* of vertebrae on which [they are] to be seated," and have "peaks to bite into the *end plates* of adjoining vertebrae."[1] A514(7:30-38). The remainder of the patent repeatedly describes the importance of seating implants on the end plates or "hard end faces" of the vertebrae, *e.g.*, A511(1:68-2:4); A513(5:22-26) A513(6:10-14), in the "disc space" or "disc column." *See, e.g.*, A511(1:51-54); A512(3:58-60); A512(4:5-8); A513(6:8-10); A513(5:28-29).

For stability, Brantigan states that the teeth improve on prior art that required cutting into the bone. A511(1:44-46). Instead, the surgeon can rely on the "ridged or peaked surfaces for biting into the vertebrae on which they are seated." A511(1:57-59). Having the implant sit within the

[1] All quoted emphasis is added unless otherwise indicated.

endplate also preserves outer disc ligaments to act as struts and provide enhanced stability. A511(2:28-33).

For bone ingrowth, Brantigan states that the "*periphery* of the oval ring is grooved to accommodate ingrowth of blood capillaries." A511(2:14-15). As noted above, the vertebral endplate is the portion of the vertebra that contains capillaries. A1306. The Brantigan patent thus makes clear that, as in claim 1, the teeth on the periphery of the implant must "bite into the *end plates* of adjoining vertebrae … to receive bone ingrowth from the vertebrae." A514(7:37-39).

Brantigan also explains that implants should sit in the endplate region because smaller implants "simplifie[d]" surgery by permitting the surgeon to "rotate[] or reverse[]" the implant and it "still fit the vertebrae." A511(2:24-25).

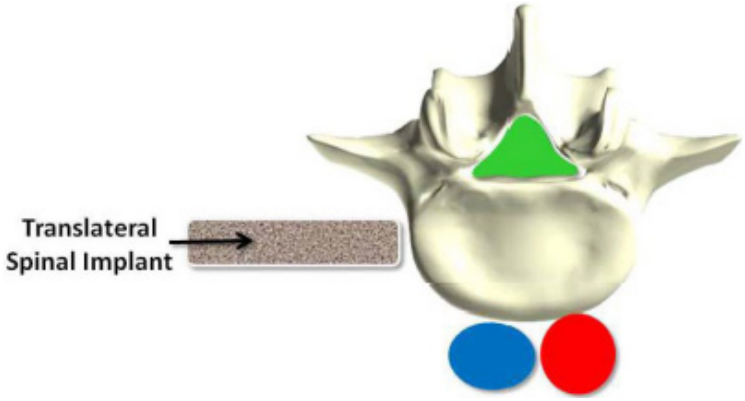
Finally, like Michelson '247, the Brantigan implants are not designed to be inserted from the side. Instead, they are to be inserted from the front or the back. The implants have a modular design so that two "hemi-oval rings can be used … side-by-side" for insertion from the back to avoid the spinal cord, A511(2:8-11), or "a single piece implant can be used" for insertion from the front. A511(2:12-14); *see also* A511(1:44-47).

* * *

In sum, before Dr. Michelson's invention, "implants … were inserted either … from the front or back, rather than the side," 778 F.3d at 1370, and intervertebral implants designed for lateral implantation did not exist. A1250 ¶45. Implants were recessed within the vertebral bodies. Nothing taught or suggested any reason to make implants larger than that, and the prior art taught several reasons not to.

D. Dr. Michelson's Inventions and the '997 Patent

From approximately 1975 to 2001, Dr. Michelson was a practicing spine surgeon. A3246; A3217. In 1993, he conceived the idea of an implant specially designed to be inserted from the side, and methods for implanting it. As the '997 patent explains, Dr. Michelson recognized that a spinal implant inserted from the side could be designed fundamentally differently from implants that surgeons inserted from the front or back. Although the vessels and spinal cord limited the *width* of a laterally-inserted implant, they did not limit the *length*. *See* A103(3:18-30); A111(20:27)-112(21:38); A100(Fig. 30).



Thus, Dr. Michelson recognized, a laterally-inserted implant could be made "oversized" so that it was not "recessed" like prior art implants. A111(20:27)-112(21:38).

Dr. Michelson further recognized, and the '997 patent teaches, that an "oversized" implant could provide benefits over prior art implants. An implant inserted from the side that was long enough to extend the full, or substantially the full, width of a vertebra—rather than a shorter implant that just rested on the vertebral endplate—would have a greater area of contact with the vertebra, and provide greater stability for the spinal fusion, with better results for the patient. A1249-50 ¶44; A112(21:33–38) ("the implant I of the present invention inserted laterally provides for greater surface area of contact, the largest volume of fusion promoting material, and the greatest mechanical engagement and thus stability, and is therefore an improvement upon other methods of implant insertion in

facilitating a successful fusion."); A112(21:33-38); A103(3:18-30) ("optimal fill of the interspace without endangering the associated structures and allow for the optimal area of contact…."); A107(11:3-8) ("maximum possible length across the transverse width W of the vertebrae."). As Dr. Sachs explained, a person of skill in the art would understand that those disclosures teach that placing the implant on the apophyseal ring and cortical rim provides greater support because that part of the bone is firmer and denser. A2620(2-10).

The '997 patent discloses and claims surgical methods using these and other insights, and explains how surgery can be performed, and implants and instruments designed, so that the instruments and implants enter the body from the side of the spine. *See, e.g.*, A103(3:34-39).

Claims 1 and 24 are reproduced on the inside covers of this brief. All claims require a direct lateral surgical path to the spine (*i.e.*, a "path having an axis lying in a coronal plane"), A112(22:60-61); A113(24:6-7); A114(25:31-32); A114(26:56-57), created by specific instruments, through which a specific lateral implant is inserted. The independent claims all follow a similar structure. Each recites a method that begins with an incision in the patient's side, followed by steps of "advancing" specific

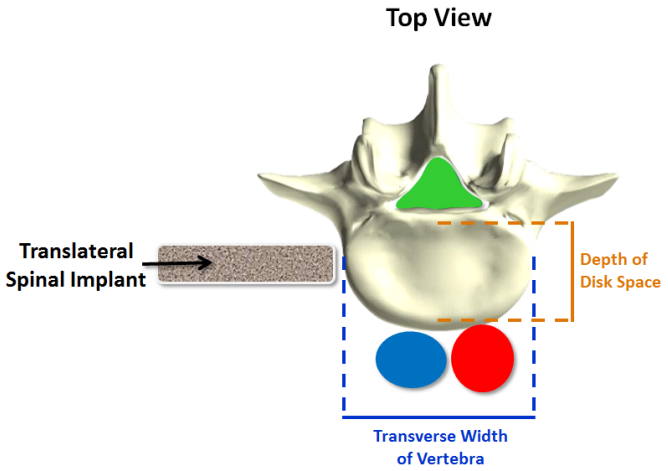
"first," "second," and "third" surgical instruments into the surgical path, and "inserting" an implant between the vertebrae to be fused.

The claims specifically define the implant to be inserted at the latter step. The claimed *length* of the implant is important to this appeal and is recited in claim 1 as follows:

> said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and *a length therebetween*,
> [i] the *length* of said implant being sized to occupy *substantially the full transverse width of the vertebral bodies* of the two adjacent vertebrae,
> [ii] the *length* of said implant being greater than the depth of the disc space, …
> [iii] said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the *length* of said implant being greater than the maximum height of said implant.

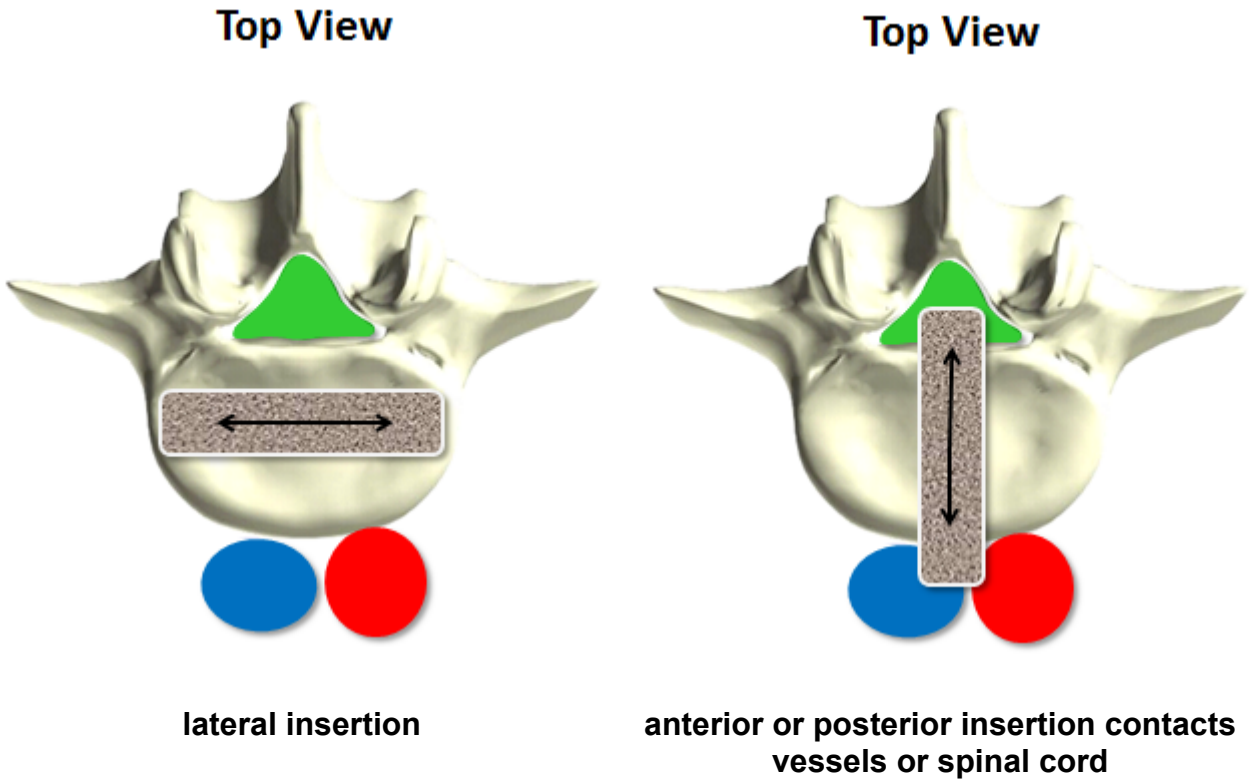
A113(23:24-30, 35-39) (roman numerals and paragraph breaks added). Claims 9 and 17 recite identical language; claim 24 recites "the full transverse width" rather than "substantially the full transverse width." As the claims recite, the "length" is measured according to the direction of insertion, from "insertion end" to "trailing end." A113(23:24-26). That length has three characteristics: for the space in which the implant is inserted, the length is (i) sized to occupy *the "full" or "substantially the full*

transverse width" of adjacent vertebral bodies, (ii) greater than the depth of the disc space, and (iii) greater than the maximum height of the implant. A113(23:24-39); A113(24:49-64); A114(26:8-24); A115(28:6-20). Those limitations embody Dr. Michelson's insights about how an implant for lateral insertion can be designed differently from prior implants. An implant inserted from the side that "occup[ies] substantially the full transverse width" of a vertebra necessarily extends beyond the vertebral endplate and sits, at least in part, on the apophyseal ring. It is only possible to use an implant whose length (from insertion end to trailing end) is "greater than the depth of the disc space" with a lateral-insertion procedure.



That is because an implant inserted from the front or back, whose length is "greater than the depth of the disc space," would protrude from the spinal column and contact the spinal cord or major blood vessels. Thus, the

implant required by the claims cannot be used in prior art procedures for inserting implants from the front or back.



In the mid-1990s, Dr. Michelson licensed and sold his patent portfolio to Warsaw. *See* A842–64. Warsaw commercialized Dr. Michelson's inventions in Europe, and later in the United States following FDA approval. A1396. Commercial embodiments have been tremendously successful. Warsaw and related entities have sold over $50M of embodying implants, while NuVasive has generated over $250M in sales of implants that practice Dr. Michelson's inventions. A1326-27; A1487-88; A1489-97.

NuVasive is Warsaw's competitor. A2853-54. NuVasive's executives are former Warsaw employees who participated in Warsaw's acquisition of Dr. Michelson's spinal surgery patents. A1257–60. When NuVasive's employees left Warsaw to form NuVasive, they built their business around Dr. Michelson's lateral technology.

To this day, Dr. Michelson's lateral fusion procedures continue to gain in popularity among spinal surgeons. A1327. Dr. Michelson's inventions ultimately improved the field of spinal surgery by facilitating a safer alternative to anterior and posterior surgeries and creating an implant that led to more stable fusion. For his inventions, Dr. Michelson has been inducted into the National Inventors Hall of Fame (housed at the USPTO), A3212:1-11, honored by the Paralyzed Veterans of America, A3213:9-14, and asked by the USPTO to teach examiners in its surgery art unit. A3214:5-3215:4.

II. Procedural History

A. *Inter Partes* Review

NuVasive filed two petitions for *inter partes* review, alleging that all claims of Warsaw's '997 patent were invalid as obvious over various combinations of prior art. *See* A167-A231; A238-A302; A4860-A4920; A4927-A4991. NuVasive challenged claims 1-8 in IPR2013-00208, and

claims 9-30 in IPR2013-00206. A4934; A243. NuVasive asserted nine grounds of invalidity in IPR2013-00208, and eight grounds in IPR2013-00206. A239-40; A4928-29. Warsaw filed preliminary responses. A644-A704; A5481-A5542.

The Board instituted *inter partes* review in both proceedings on all claims, on subsets of NuVasive's proposed grounds, as shown below:

Ground	Claims	Prior Art Combinations
IPR2013-00208		
1	1 and 8	Jacobson, Leu, and Brantigan
2	1 and 8	Jacobson, Leu, and Michelson '247
3	2-7	Jacobson, Leu, Brantigan, and Frey
4	2-7	Jacobson, Leu, Michelson '247, and Alacreu
IPR2013-00206		
1	9 and 16	Jacobson, Leu, McAfee, and Michelson '247
2	10-15	Jacobson, Leu, McAfee, Michelson '247, and Frey
3	17 and 23	Jacobson, Leu, and Brantigan
4	18-22	Jacobson, Leu, Brantigan, and Frey
5	24 and 30	Jacobson, Leu, and Michelson '247
6	25-29	Jacobson, Leu, Michelson '247, and Frey

See A970-71 (IPR2013-00206); A5810 (IPR2013-00208).

For each allegedly obvious combination, NuVasive relied on either Brantigan or Michelson '247 (but not both) to argue that prior art disclosed the implant-related claim limitations.

For claims 9-16 and 24-30, NuVasive's theory was that Michelson '247 disclosed the claimed implants. *See* A260-61; A279-80; A5; A31-33. The Board rejected NuVasive's arguments. Michelson '247 discloses *posterior* cylindrical implants that are "recessed into the vertebral bodies," A533(10:31-36); A1313 ¶118—in effect the opposite of the oversized dimensions of the *lateral* implants claimed in the '997 patent. The Board examined Michelson '247 and the parties' evidence and arguments, and concluded that Michelson '247 does not disclose the "substantially the full transverse width" limitation, explicitly or implicitly. A31-33 (final decision); A38-44 (denying NuVasive's rehearing request).

For claims 1-8 and 17-23, NuVasive relied on Brantigan for the claimed implants. Although Brantigan discloses an implant that sits only on a vertebra's endplate, the Board concluded that Brantigan discloses implants that occupy "substantially the full transverse width" of vertebral bodies, as the claims of the '997 patent recite. A16-A21. The Board relied on a statement in Brantigan that the disclosed spinal implants are "sized to conform with the disc space." A20; A61. The Board found that "one of ordinary skill in the art would have understood [that phrase] to mean sized to occupy substantially the full transverse widths of the vertebral

bodies," A21; A64, and went on to conclude that a person of skill would have combined Brantigan with other prior art to arrive at the inventions of claims 1-8 and 17-23.

The Board never found that Brantigan, or any other prior art, disclosed an implant with a *length*—measured from the implant's insertion to trailing ends, as recited in the claims—of "substantially the full transverse width" of adjacent vertebral bodies. Nor did the Board ever identify a reason why a skilled artisan would have modified the prior art references to arrive at that claimed length. A23-A24; A66-67. Instead, the Board held that claims 1-8 and and 17-23 were merely "combination[s] of familiar elements according to known methods … [that do] no more than yield predictable results." A24; A67.

The Board did not address Warsaw's argument that Brantigan does not disclose an implant with a length greater than the depth of the disc space. The Board acknowledged that Brantigan disclosed an implant that can be "rotated or reversed and still fit the vertebrae," but did not understand the significance of that—namely, that such an implant *necessarily could not* have a length exceeding the depth of the disc space.

B. Related Litigation

Warsaw's '973 patent is related to the '997 patent here. The '973 patent includes apparatus claims drawn to an oversized spinal implant capable of being inserted laterally in the '997 method. A880-82.

In district court litigation regarding the '973 patent, NuVasive made similar arguments about the prior art Brantigan reference to those it makes in this case. In support of an inequitable conduct defense, NuVasive argued that the '973 patent specification falsely stated that all prior implants had been inserted from either the front or the back of the patient. A907. That was false, NuVasive alleged, because Brantigan "teaches spinal fusion implants capable of insertion from the lateral aspect of the spine," and Michelson and his patent attorneys were aware of Brantigan. *Id.* The district court rejected those arguments after a bench trial, and NuVasive did not appeal that ruling. *Id.*

SUMMARY OF THE ARGUMENT

The Board properly ruled that NuVasive failed to meet its burden of proof to invalidate claims 9-16 and 24-30. The scope and content of prior art and the differences between prior art and the claims are questions of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). NuVasive argued that Michelson '247 taught a critical element of the claims—a lateral

implant with specific dimensions relative to its direction of insertion and placement in the body. The Board weighed the parties' evidence and testimony on that score and properly ruled against NuVasive on the facts—Michelson '247 did not disclose the claimed lateral implant explicitly or implicitly, and NuVasive failed to provide persuasive evidence and rational explanations to fill that gap in the prior art. Substantial evidence supports the Board's findings, and affirming should be a straightforward matter. NuVasive makes several arguments to avoid confronting the Board's analysis head-on—it accuses the Board of undue "rigidity," faults the Board for failing to raise certain arguments *sua sponte*, and launches a broadside attack on the PTAB's institution procedures—an argument it never raised below. NuVasive's appeal, thus, founders on a straightforward application of precedent and review for substantial evidence, and the Board's rulings as to claims 9-16 and 24-30 should be affirmed.

As to claims 1-8 and 17-23, the Board misread the Brantigan reference, misapplied *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), and fell into the classic trap of hindsight. Those claims recite a lateral implant, specially designed according to Dr. Michelson's insights, that

simply did not exist in the prior art. The Board's obviousness ruling should be reversed for two independent reasons as to claims 1-8 and 17-23, and a third reason as to claims 17-23:

First, Brantigan does not disclose an implant that meets the limitations of the implant element in claims 1-8 and 17-23. It has no dimension, much less a length, that is substantially the full width of a vertebra. And it does not teach, disclose, or suggest that the length must be greater than the depth of the disc space. Nor did the Board find any reasons why a person of ordinary skill in the art would modify Brantigan's implant—substantially redesigning and reorienting it—to meet the claimed limitations. The Board's conclusion that the claims merely recite "familiar elements" combined by known methods with predictable results is not supported by substantial evidence.

Second, the Board's determination that a person of ordinary skill in the art would have found it obvious, *ex ante*, to combine Jacobson, Leu, and Brantigan is the product of impermissible hindsight. The Board cites *nothing* to support its conclusion. Rather, the Board assumes the conclusion that a skilled artisan would believe that the needle-puncture procedures disclosed in Jacobson would be appropriate for a large implant;

and likewise assumes that the Brantigan implant is even capable of lateral insertion.

Third, with respect to claims 17-23, the Board's finding that Jacobson discloses positioning the claimed elongated elements over adjacent vertebral bodies is not supported by substantial evidence. The Board found that Jacobson's disclosure of "anchor wires," which are positioned over and inserted into the disc capsule, disclose this limitation, but the evidence unmistakably shows that the anchor wires are inserted *into the disc capsule, not over adjacent vertebrae*. The Board's conclusions, thus, are either unsupported by substantial evidence or predicated on an erroneous, implicit construction of the "elongated portions" claim element.

STANDARD OF REVIEW

Obviousness is ultimately a question of law, reviewed *de novo*. *In re Woodruff*, 919 F.2d 1575, 1577 (Fed. Cir. 1990). Underlying factual determinations are reviewed for substantial evidence. *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015). The "substantial evidence standard requires the reviewing court to ask whether a reasonable person might find that the evidentiary record supports the agency's conclusion." *On-Line Careline, Inc. v. Am. Online,*

Inc., 229 F.3d 1080, 1085 (Fed. Cir. 2000). Substantial evidence is "more than a mere scintilla." *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

For claim construction, the Court reviews "underlying factual determinations concerning extrinsic evidence for substantial evidence and the ultimate construction of the claim *de novo*." *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1282-83 (Fed. Cir. 2015).

ARGUMENT

A claim is only obvious "if the differences between the claimed invention and the prior art are such that *the claimed invention as a whole* would have been obvious *before the effective filing date* of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103.

KSR set forth a "flexible approach" to obviousness. 550 U.S. at 401-03. A claim composed *solely* of "familiar elements"—*i.e.*, elements explicitly in the prior art—combined according to known methods is obvious when it merely yields entirely predictable results. *Id.* at 401. Where a claim element is not disclosed in the prior art, the claim may still be obvious, but the patent challenger must identify a reason for modifying the prior art to have such an element. *Id.* at 417–18; *Plantronics, Inc. v.*

Aliph, Inc., 724 F.3d 1343, 1354 (Fed. Cir. 2013) ("[C]onclusions with respect to obviousness must find support in the record … we cannot simply assume that 'an ordinary artisan would be awakened to modify prior art.'"); *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1304–05 (Fed. Cir. 2011). In other words, although every claim limitation need not be disclosed in the prior art, precedent requires *a reason or motivation* to fill a gap in the prior art before finding a claim obvious. *Plantronics*, 724 F.3d at 1354; *Genetics Inst.*, 655 F.3d at 1304-05.

Here, not all of the elements are disclosed, nor was there any reason to modify the prior art to achieve Dr. Michelson's result, except by retracing Dr. Michelson's steps through hindsight. But one cannot look at the claimed invention and work backwards. *See KSR*, 550 U.S. at 421 ("A factfinder should be aware … of the distortion caused by hindsight bias and must be cautious of arguments reliant on *ex post* reasoning."); *Leo Pharm. Prods, Ltd. v. Rea*, 726 F.3d 1346, 1354 (Fed. Cir. 2013) ("[The Board erred by collapsing the obviousness analysis into a hindsight-guided combination of elements."); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1073 (Fed. Cir. 2012)

("retrac[ing] the inventor's steps" is impermissible "hindsight"); *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012).

The statutory language "before the effective filing date," 35 U.S.C. § 103, is an explicit directive to avoid hindsight.[2] Rather, the obviousness analysis requires a specific, persuasive, explanation why a person of ordinary skill would have combined or modified the prior art to arrive at the claimed invention. *Cyclobenzaprine*, 676 F.3d at 1068-69.

I. The Court Should Affirm the Board's Ruling that NuVasive Did Not Demonstrate the Unpatentability of Claims 9-16 and 24-30.

A. The Board's Decision Regarding Claims 9-16 and 24-30 is Correct.

1. The Board's Decision is Supported by Substantial Evidence.

The Board properly rejected NuVasive's argument that Michelson '247 taught the "implant" limitations of claims 9-16 and 24-30 or otherwise rendered those claims obvious. NuVasive's argument was twofold: (1) Michelson '247 teaches that implants should be made as large as possible in the dimension from the front to the back of the vertebrae, and (2) a

[2] The America Invents Act amended 35 U.S.C. § 103. The pre-AIA version used "at the time the invention was made"— an equally explicit directive to avoid hindsight.

skilled artisan would apply this alleged teaching to a lateral fusion procedure to meet the claimed implant length when it was attempted along a different dimension. *See, e.g.*, A260-61. The Board found NuVasive's argument failed—based on the facts—at the first step. After considering the Michelson '247 patent disclosure and the competing expert testimony, the Board concluded that this critical teaching did not exist, explicitly or implicitly where NuVasive urged the Board to look for it: "Petitioner … does not demonstrate persuasively that Michelson '247 discloses *or suggests* an 'implant being sized to occupy the full' (or 'substantially full') dimension of the vertebral body, as recited in claim 9 or claim 24." A33. To the contrary, the Michelson '247 reference teaches using implants "recessed" within the vertebrae. A32. The Board's findings are amply supported by substantial evidence.

As described above, all claims of the '997 patent recite that the implant's "length"—from insertion end to trailing end—must be "sized to occupy substantially the full transverse width" of a vertebra. The claims, thus, capture one of Dr. Michelson's key insights about how an implant can be specially designed for lateral insertion with an oversized "length."

Michelson '247 teaches something close to the opposite approach. As the Board noted, A32, Michelson '247 discloses implants inserted from the rear and "recessed into the vertebral bodies" for safety, A533(10:31-36); A1313 ¶118. Further underscoring that conclusion, Michelson '247 teaches that a 27 to 28 mm bore hole for inserting a threaded implant "seems to be safe for probably 3 standard deviations of the population," but that the borehole and implant could be *shortened* "for enhanced safety." A533(9:39-46); A32; *see also* A1313 ¶118. Far from teaching a skilled artisan to lengthen the implant as much as possible, the Board properly concluded that Michelson '247 teaches the opposite. A32.

As the Board observed, the expert testimony further supports that conclusion. A32-33. NuVasive's expert McAfee testified that Michelson '247 does *not* teach to "span as much of the length from anterior to posterior direction of the intervertebral space as possible." A3048(6-16). Warsaw's expert Sachs explained that Michelson '247 "expressly teaches that the length of the implant 50 should be *less than the depth of the disc space*." A1313 ¶118; A533(10:31-36). Sachs further explained that a surgeon would not insert an implant that approximated the depth of the disc space because doing so would be too risky—any movement of the

implant could injure the aorta or vena cava in front of the spine or the spinal cord in back. A1313 ¶118. Michelson '247 simply does not teach that implants should be made as long as possible (it teaches the opposite), nor does it suggest anything about how to size or structure a laterally-inserted implant. The Board was not required to conclude otherwise.

Based on two drawings NuVasive argues that the Board erred as a factual matter. NuVasive Opening Br. 27-29. Essentially, NuVasive has taken a ruler to figure 5 of Michelson '247 and figure 23 of the '997 patent to argue for a new claim construction of "substantially" in the '997 patent, and to argue that the Board misread Michelson '247. NuVasive is wrong on both points.

The Board accepted NuVasive's construction of "sized to occupy *substantially* the full transverse width of the vertebral bodies" as referring to implants that "may occupy the full transverse width but also may occupy only a length that is less than the full transverse width of the vertebral bodies by an insubstantial amount." A957 (institution decision); A6. On appeal, NuVasive attempts to supplement that construction. Based on its own measurements of Figure 23 of the '997 patent, NuVasive argues that that "substantially the full transverse width" in the '997

patent claims must include as little as 73% of the full transverse width because that is what NuVasive says "Figure 23 … shows the claimed implant occupying." NuVasive Opening Br. 29. NuVasive likewise argues that Figure 5 of Michelson '247 "expressly teach[es] the skilled artisan to use an implant should [*sic*] span substantially the full dimension of the disc space in the direction of insertion" because—NuVasive argues—that picture appears to depict an implant spanning substantially the full depth of the vertebrae. *Id.* at 27.

Those arguments are unsound for at least three reasons. *First*, this Court has repeatedly explained that such "arguments based on drawings not explicitly made to scale in issued patents are unavailing." *Nystrom v. TREX Co., Inc.*, 424 F.3d 1136, 1139 (Fed. Cir. 2005)*; Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000)*; Go Med. Indus. Pty. v. Inmed Corp.*, 471 F.3d 1264, 1271 (Fed. Cir. 2006). The written descriptions of both patents explain what the respective figures show, and neither figure 5 of Michelson '247 nor figure 23 of the '997 patent purports to be to scale.

Second, this Court has held that "substantially" "is a meaningful modifier implying 'approximate,' rather than 'perfect.'" *Playtex Prods., Inc.*

v. Procter & Gamble Co., 400 F.3d 901, 907 (Fed. Cir. 2005). The Court has rejected constructions of "substantially"—like the one NuVasive advances on appeal—that add "numerical tolerance[s] or "strict numerical boundar[ies]." *Id.* (collecting cases). Further, having successfully argued for a different construction below, NuVasive cannot argue on appeal for a new construction that adds numerical boundaries to the term "substantially."

Third, the record evidence refutes NuVasive's contention that figure 5 of Michelson '247 is sufficient to teach the length of the '997 patent's claimed implants. NuVasive's own expert testified that a drawing, standing alone, is insufficient. A3047:5-23. Prior art must be read as a whole, *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987), and Michelson '247 is explicit in its teachings to recess the implant in the disc space, not maximize the implant's size. *E.g.*, A533(10:31-36); A533(9:39-46). Similarly, Dr. Sachs testified that a skilled artisan would not rely on Figure 5 to discern the teachings of Michelson '247, as inserting an implant as shown in Figure 5 in an anterior-posterior orientation would carry unjustifiable risk of patient injury. A1313-14 ¶118.

At best, NuVasive simply raises a factual dispute that the Board was entitled to resolve against NuVasive. Because Michelson '247 teaches an implant recessed within the vertebrae, and possibly shortened for safety reasons, the Board properly found Michelson '247 could not support an argument that a skilled artisan would know to make an implant substantially the full length of any dimension of a vertebra, much less the width. In any event, there is no argument that the Michelson '247 implant is longer than the depth of the disc space—it cannot be and be used as intended. NuVasive did not meet its burden of proof, and the Board was entitled to conclude as much.

2. NuVasive's Factual Arguments Regarding Michelson '247, Made For the First Time in Reply at the PTAB, Are Waived and Meritless.

NuVasive makes two arguments about Michelson '247's disclosure on appeal that were first presented in its reply at the PTAB. NuVasive's timing violated the PTAB's rules and deprived Warsaw of any opportunity to respond with evidence or argument.[3] NuVasive's arguments are meritless in any event, and the Board properly rejected them.

[3] The IPR trial rules do not allow a substantive patent owner filing after its response to a petition. *See* 37 C.F.R. § 42.1 *et seq.* NuVasive's late

First, NuVasive argues that Michelson '247's statement that "the present invention offers considerably greater surface area to distribute the load," teaches a skilled artisan to lengthen prior art implants. NuVasive Opening Br. 29-30. The Board properly rejected that argument. A40. As the Board found, Dr. Michelson's reference to "greater surface area" means to insert *two implants* "bilaterally" (*i.e.*, inserted from back-to-front, and placed side-by-side). *See* A526(Fig. 4); A40. In other words, "greater surface area" is achieved through implanting two implants, not increasing the size of a single implant. Michelson '247 makes no suggestion of spanning the full (or substantially the full) depth, which would risk injury to the major blood vessels or spinal cord. For example, the specification states that "*the present invention*" has greater surface area than the Bagby implant. A531(5:2-4). The "present invention," however, is not a single cylindrical implant; it is *two* cylindrical implants placed in parallel. A530(3:23–26) ("the present invention" includes the described implants, instrumentation, and method). Michelson '247 neither states that a single implant alone has more surface area than the prior art Bagby implant nor

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presentation of these arguments precluded Warsaw from seeking expert testimony on these positions. Warsaw's expert, Dr. Sachs, had no opportunity to opine on these new interpretations of Michelson '247.

teaches that its implants are longer than the Bagby device—"greater surface area" is achieved by inserting two implants, not making those implants larger. (A531 at 5:2–4.)

Second, NuVasive argues that Michelson '247's teaching that the "present device is placed bilaterally where the bone tends to be more cortical and much stronger out towards the rim" suggests to a skilled artisan to size an implant to rest on the cortical or apophyseal ring. NuVasive Opening Br. 30. Not so: the stronger bone "*towards* the rim" (*i.e.*, not on the rim itself) is within the endplate and is reached by placing two cylindrical implants parallel to each other, but spaced apart so they reach the side edges of the endplate, not by lengthening an implant to span any dimension of the disc space. A531(5:4-7). That aspect of Michelson '247 was an improvement over the prior art Bagby device, which was "placed centrally" on the softest, bone in the middle of the endplate. *Id.* The Board rightly concluded that that aspect of Michelson '247's disclosure indicates "the location at which the device is placed (*i.e.*, bilaterally) and does not refer to the size of the device." A41.

3. The Board Applied the Correct Legal Standard.

Recognizing the weakness of its position, NuVasive attempts to turn its disagreement with the Board's weighing of evidence into a legal issue by arguing that the Board applied a "rigid analysis" limited to the "express disclosures" of Michelson '247. NuVasive Opening Br. 22-27. NuVasive misstates the law and the Board's ruling, and its real argument appears to be that the Board should have credited NuVasive's expert's conclusions.

NuVasive correctly notes that this Court and the Supreme Court have cautioned against a "rigid" approach to obviousness that fails to account for the "inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418. NuVasive incorrectly suggests that the Board employed any such approach to claims 9-16 and 24-30.

The supposed "ordinary creativity" that NuVasive claims the Board ignored consists entirely of NuVasive's expert testimony and NuVasive's attorney-argument appeals to hindsight. NuVasive summarizes the Board's "error" as follows:

> The Board should have instead asked whether a skilled artisan familiar with Michelson '247 who was contemplating performing a lateral fusion surgery would have applied his ordinary creativity to select an implant with that length.

> NuVasive submitted expert testimony that a skilled artisan *would* have done so.

NuVasive Op. Br. 24 (original emphasis). NuVasive goes on to quote a paragraph of its expert's testimony, emphasizing that the expert used buzzwords such as "based on my knowledge and experience in this field" and "would have been predictably selected." *Id.* at 25. The Board was certainly not required to credit that testimony. *Whitserve LLC v. Computer Packages, Inc.*, 694 F.3d 10, 24 (Fed. Cir. 2012) (quoting *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1152 (Fed. Cir. 2004)). NuVasive's reasoning assumes the conclusion that a skilled artisan would contemplate laterally inserting an implant in the first place and then would favor an oversized implant over a different design philosophy. NuVasive offers no reason why a skilled artisan would deviate from Michelson '247's contrary teaching to recess the implant into the vertebral body.

Beyond asserting that the PTAB should have been more impressed by NuVasive's expert testimony, NuVasive asks the Court to engage in hindsight by using Dr. Michelson's own inventive process and the '997 patent disclosure as evidence of obviousness. NuVasive speculates that "the '997 inventor simply modified his own posterior implant in a

predictable way that was consistent with human anatomy." NuVasive Opening Br. 25-26. And NuVasive attempts to support its argument by quoting from the '997 patent. *Id.* at 25 ("[T]he '997 patent itself acknowledges … that it 'can be appreciated' by the skilled artisan that a laterally inserted implant 'may be of a much greater length… than implant 1090 inserted from anterior to posterior."). That speculation and NuVasive's reliance on the '997 patent are improper. This Court's precedent unequivocally holds that retracing the inventor's own path or using the patent's disclosure as a roadmap for the prior art amounts to impermissible hindsight. *See, e.g.*, *Cyclobenzaprine*, 676 F.3d at 1073 ("retrac[ing] the inventor's steps" is impermissible "hindsight"); *Otsuka*, 678 F.3d at 1296 ("The inventor's own path itself never leads to a conclusion of obviousness; that is hindsight."); *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1348-49 (Fed. Cir. 2014). NuVasive cannot rely on "the '997 patent itself" and what NuVasive believes "the '997 inventor simply [did]," to prove obviousness. NuVasive Opening Br. 25. The gap between the prior art and a claimed invention may be bridged by credible evidence of how a person of skill in the art would have approached

a problem at the time of the invention—not by hindsight or attorney argument.

4. NuVasive's Arguments Regarding Brantigan Are Barred and Meritless.

NuVasive argues that the Board should have considered the Brantigan patent in its analysis of claims 9-16. NuVasive Opening Br. 22, 26. As explained in Section III.A, *infra*, Brantigan cannot support a finding of obviousness. If the Court agrees, NuVasive's arguments for applying Brantigan to claims 9-16 are necessarily moot.

Regardless, the reason the Board did not consider the Brantigan reference against claims 9-16 is that was not the theory NuVasive pursued. NuVasive chose to assert Brantigan as part of combinations that allegedly invalidated claims 1-8 and 17-23, but *not* claims 9-16 or 24-30. Because NuVasive did not ask the Board to institute review of claims 9-16 as based on combinations including Brantigan, A953-54, the Board did not do so. A970. NuVasive's arguments are thus jurisdictionally foreclosed here. *See* 35 U.S.C. § 314(d)(the determination whether to institute inter partes review "shall be final and nonappealable"). In *In re Cuozzo*, this Court held that Section 314(d) means what it says and "exclude[s] *all* review of the decision whether to institute review." 778 F.3d at 1276.

NuVasive having not sought review of claims 9-16 on grounds that relied on the Brantigan reference, and the Board having therefore not instituted review on those grounds, NuVasive cannot now argue on appeal that the Board erred by not considering the Brantigan reference.

Even if not jurisdictionally foreclosed, NuVasive's argument that the Board should have mixed and matched NuVasive's prior art references *sua sponte* to invalidate claims 9-16 is contrary to basic substantive and procedural principles.

First, a claim is not proved obvious "merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. Instead, patent challengers must identify specific references and specific reasons to combine or modify those references. *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012). For claims 9-16 and 24-30, NuVasive did not identify Brantigan as any relevant part of the analysis. It would be fundamentally inconsistent with precedent (and unfair to Warsaw) for the Court to now hold that the Board erred by failing to mix and match references *sua sponte* to construct new obviousness theories for NuVasive and to invalidate claims on the basis of evidence and explanations NuVasive never provided.

Second, basic principles of appellate review and waiver preclude NuVasive from asserting error on the basis of arguments it never made. Appellate courts do not sit to review matters not presented below. *Mass. Mut. Life Ins. Co. v. United States*, 782 F.3d 1354, 1369 (Fed. Cir. 2015). Consistent with precedent, the PTAB's rules (1) require parties to identify in their petitions specific claims, specific grounds of invalidity, and specific supporting evidence, 37 C.F.R. § 42.104(b), and (2) provide that the PTAB decides at institution which claims and which grounds of invalidity will proceed. 37 C.F.R. § 42.108. NuVasive made a strategic choice to make arguments based on Brantigan against some claims and based on Michelson '247 against others. Adversarial proceedings are "designed around the premise that the parties know what is best for them, and are responsible for advancing the facts and arguments entitling them to relief." *Greenlaw v. United States*, 554 U.S. 237, 243-44 (2008). Adjudicators are not "self-directed boards of legal inquiry and research, but … arbiters of the legal questions presented and argued by the parties before them." *Carducci v. Regan*, 714 F.2d 171, 177 (D.C. Cir. 1983) (Scalia, J.). Here, the Board properly followed its own procedures and evaluated NuVasive's arguments and evidence as presented. That is not

"rigidity and formalism," NuVasive Opening Br. 26, but orderly adjudication and the result of NuVasive's strategic choices. The Board was not required to mix and match prior art to construct new arguments *sua sponte*, and it would have been unfair to Warsaw had the Board done so.

B. NuVasive's Additional Arguments Regarding Claims 24-30 Are Without Merit.

Claims 24-30 differ from the other claims by reciting an implant that spans "the *full* transverse width" of adjacent vertebral bodies, not just "substantially" the full width. A115(28:8-10). By NuVasive's admission, neither Michelson '247 nor Brantigan—the two references NuVasive relied upon for the implant limitations—teach or suggest the insertion of an implant that spans *any full dimension* of adjacent vertebral bodies. NuVasive Opening Br. 8, 10. NuVasive has recently admitted that Michelson '247 only teaches a surgeon to "span nearly the full distance across the disc space, *but not all the way*." *See* Request For *Ex Parte* Reexamination of U.S. Patent No. 5,860,973, Serial No. 90/013,464, at 143 (Mar. 6, 2015). That, of course, is insufficient for claims 24-30. A115(28:8-10); A3045(42:6–9). And again, Michelson '247 actually teaches away from this limitation by instructing that its implants should be recessed into the

vertebral bodies, and shortened for safety. A533(10:31-36); A533(9:42-43); A1313 ¶118. Thus, even if the Board somehow erred in its reading of Michelson '247, any error would be necessarily harmless as to claims 24-30. Thus, regardless of how the Court views claims 9-16, the Board's decision with respect to claims 24–30 should be affirmed on this independent ground.

II. NuVasive's Arguments About the PTAB's Institution Procedures For Claims 9-16 and 24-30 Are Waived and Meritless.

NuVasive's fallback argument for claims 9-16 and 24-30 is that the PTAB must always revisit redundant grounds of invalidity whenever it finds a petitioner has not met its burden as to instituted grounds. Setting aside whether the PTAB's decision to institute review on some grounds but not others is even appealable, *see* 35 U.S.C. § 314(d), NuVasive's arguments are waived. The challenges NuVasive makes to the Board's institution procedures were not raised below, and the Board was thus not given an opportunity to address NuVasive's arguments. This Court should not do so in the first instance, either on appeal or by treating NuVasive's brief as a mandamus petition.

A. NuVasive's Arguments Are Waived and Meritless.

Appellate courts are "court[s] of review, not of first view." *Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005). "If a litigant seeks to show error in a trial court's overlooking an argument, it must first present that argument to the trial court." *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1426 (Fed. Cir. 1997). NuVasive had (at least) two opportunities to raise its "redundancy" arguments to the Board, but sat silent instead. That is reason enough to reject its arguments here.

Inter partes review occurs in two parts: "preliminary" and "trial" phases. 37 C.F.R. § 42.2 (definitions of "trial" and "proceeding"). In its institution order, the Board chose to institute trial as to some, but not all, of the grounds in NuVasive's petition. A969-71. NuVasive could have asked the Board to reconsider that ruling, 37 C.F.R. § 42.71(d)(1), and could have argued—as it now argues on appeal—that the Board's "redundancy" doctrine is not in the statute and threatens to deprive NuVasive of certain rights. But NuVasive filed nothing at that point.

After the Board rendered its final decision, NuVasive again could have argued—as it now does on appeal—that the reasoning of the final decision required the Board to go back and reconsider grounds on which it

declined to institute trial. *Id.* § 42.71(d)(2). And, of course, NuVasive could have disputed the propriety of the Board's redundancy doctrine. NuVasive *did* file a request for rehearing on other grounds, A4831-49, but did not raise the procedural issues it raises on appeal.

NuVasive points to three sentences in its reply below, where it made an unexplained, contingent "request that the Board consider the validity of claims 24-30 under Ground 8." NuVasive Opening Br. 34 (citing A1689). But unexplained statements of position do not preserve arguments for appeal. *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) (citing five circuits' cases). Nothing in NuVasive's reply below even hints at the arguments NuVasive makes on appeal. NuVasive never argued to the Board, as it does now, that the "'redundancy' doctrine appears nowhere in the statute," NuVasive Opening Br. 38, that NuVasive faces some threat of estoppel in district court, *id.*, that any "statutory command" exists that "requires the Patent Office to at least address, in some form, all arguments raised by a petitioner," *id.* at 39, or that NuVasive has any due process or statutory entitlement to have "redundant" grounds in its petition treated as retroactive fallback arguments after trial. Had NuVasive made the arguments it now makes,

the Board (and Warsaw) might have been able to address them. NuVasive's appeal brief is not the appropriate time or place to make those arguments for the first time.

NuVasive's arguments are unsound on the merits in any event. NuVasive's analogy to district court litigation is also inapt. The two-stage format of *inter partes* review at the PTAB is not analogous to a district court that resolved a case on one alternative ground before being reversed by an appellate court. In the preliminary stage of *inter partes* review, as the statute requires, 35 U.S.C. § 314, the PTAB determines whether there is a "reasonable likelihood" that grounds in the petition will invalidate challenged claims. The later, final decision after trial is not the Board exercising appellate review of its earlier decision to institute, but rather the Board's adjudication of the claims and grounds on which it chose to proceed. By regulation—which NuVasive does not challenge or even cite—the Board applies discretion in its institution decision to shape the instituted "trial" efficiently. *See* 35 U.S.C. § 316; 37 C.F.R. § 42.108(b) ("At any time prior to institution of *inter partes* review, the Board *may* deny some or all grounds for unpatentability for some or all of the challenged claims."). The PTAB has consistently maintained that it has discretion

with respect to the scope of institution. *HTC Corp. v. Flashpoint Tech.*, IPR2014-934, 2015 WL 1276995, at *2-3 (P.T.A.B. Mar. 10, 2015); *Intelligent Bio-Sys. v. Illumina Cambridge Ltd.*, IPR2013-324, 2013 WL 8563954, at *3 (P.T.A.B. Nov. 21, 2013); *Valeo N. Am., Inc. v. Magna Elecs., Inc.*, IPR2014-1206, 2014 WL 7336080, at *5 & n.16 (P.T.A.B. Dec. 23, 2014). NuVasive did not argue below that the PTAB lacks discretion in its institution decisions, and it does not argue that now. In sum, NuVasive's challenges to the Board's procedures are not preserved for appeal, and are meritless in any event.

B. NuVasive is Not Entitled to a Writ of Mandamus.

"[T]he writ of mandamus is an extraordinary remedy, to be reserved for extraordinary situations." *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 289 (1988). Only a clear abuse of discretion that causes a "'judicial usurpation' of power will justify the invocation of this extraordinary remedy." *Will v. United States*, 389 U.S. 90, 95 (1967). A petitioner must show (1) it has no other adequate means to attain the relief it desires, (2) it has a "clear and indisputable" right to issuance of the writ, and (3) the writ is appropriate under the circumstances. *In re*

Cuozzo, 778 F.3d at 1277-78. NuVasive's alternative request for mandamus, NuVasive Opening Br. 37-39, fails on each point.

First, as just discussed, NuVasive could have asked the Board at multiple junctures for the relief it now requests, but failed to do so. *See* 37 C.F.R. § 42.71(d)(1) - (2). Having passed up at least two opportunities "to obtain the relief it desires," NuVasive cannot now argue that the Board's procedures are "inadequate" for purposes of mandamus.

Second, NuVasive's "right" is anything but "clear and indisputable." At most, NuVasive's assertion of a "right" to hold "redundant" arguments in reserve for later consideration by the PTAB raises a novel question—the opposite of a "clear and indisputable" right. NuVasive's assertion of a "right" also relies heavily on the contention that it may be estopped in district court. NuVasive Br. 38. But that contention is certainly not "clear and indisputable," for at least the reason that the PTO consistently disputes it. *See, e.g.*, Br. for Intervenor Director of USPTO, at 38-40, *Schott Gemtron Corp. v. SSW Holding Co.*, Appeal No. 15-1073, Dkt. No. 44 (filed Apr. 9, 2015).

Finally, mandamus is not "appropriate under the circumstances." NuVasive's conclusory due process and fairness arguments ignore that

inter partes review has always been discretionary and to the extent NuVasive risks estoppel, NuVasive assumed that risk in filing its petitions. The Board has rejected arguments similar to NuVasive's:

> While we understand Petitioner's point of view, it made a litigation choice to file an *inter partes* review petition. Our rules, as promulgated, indicate that there is no requirement that all grounds be instituted ..."

HTC, 2015 WL 1276995, at *4. Although *HTC* does not bind this Court, its reasoning is sound: NuVasive made a calculated decision to seek *inter partes* review, knowing that its request depended, to some extent, on the PTAB's discretion and knowing of a risk of estoppel. *See* 35 U.S.C. §§ 314(a), 315(e). NuVasive's due process arguments do not support the extraordinary relief of mandamus.

III. The Court Should Reverse the Board's Ruling that Claims 1-8 and 17-23 Are Obvious In Light Of Combinations That Include Brantigan.

The Board's conclusion that claims 1-8 and 17-23 are unpatentable depends on its finding that Brantigan discloses an implant meeting the limitations recited in claims 1-8 and 17-23. That finding is based on a misreading of the Brantigan patent, a failure to apply all limitations of claims 1-8 and 17-23, and a fundamental misunderstanding of Warsaw's arguments. The '997 patent claims recite an implant that not only must

(1) have some dimension that substantially spans the full transverse width, but (2) that dimension must be its length (defined as measured from leading to trailing end), and (3) that length must be greater than the depth of the disc space. The Board ignored the second and third requirements, and read Brantigan to meet the first requirement based on a basic misunderstanding of anatomy. Once the factual predicates for the Board's obviousness ruling are gone, the ruling must be reversed.

Regardless, neither Brantigan nor anything else NuVasive or the Board cited would suggest modifying implants to make the oversized lateral implant required by the claims. Nor does the Board offer any reasoning to support its conclusion that a person of ordinary skill in the art would combine the Jacobson, Leu, and Brantigan references in the first place. Ultimately, the Board's decision depends on the kind of hindsight-based reasoning barred by this Court's precedents.

A. Brantigan Does Not Disclose An Implant With The Limitations Of Claims 1-8 and 17-23.

The Board's finding that Claims 1-8 and 17-23 represented combinations of known elements, A23, relies entirely on the premise that Brantigan disclosed the claimed implant. Because Brantigan does not—

for any of three independent reasons addressed below—the obviousness determination cannot stand.

1. Brantigan Does Not Disclose An Implant With Any Dimension Spanning "Substantially the Full Transverse Width" Of A Vertebra.

Under the Board's construction, the implant of claims 1-8 and 17-23 must have a "length that is less than the full transverse width of the vertebral bodies by an *insubstantial amount*." A957, A5799; A2619-21. There is no substantial evidence in the record that Brantigan discloses an implant with *any* dimension (much less its length, *see* § II.A.2, *infra*) that spans substantially the full transverse width of a vertebra.

Substantial evidence is "something less than the weight of the evidence but more than a mere scintilla of evidence." *Kotzab*, 217 F.3d at 1369; *see also Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229-30 (1938). The *only* evidence the Board relied on to find that Brantigan disclosed implants that are substantially the full width of the vertebrae was a statement in Brantigan that its implants are "generally shaped and sized to conform with the disc space." A16; A20; A61; A64; *see* A512(4:5-8).[4]

[4] That argument first appeared in NuVasive's reply briefs below. A1687; A6512. In several instances, the Board stated that Warsaw did not

Citing no evidence, the Board made the leap to say that a person of ordinary skill in the art would necessarily understand that "'sized to conform with the disc space,' … mean[s] sized to occupy substantially the full transverse widths of the vertebral bodies." A20-21; A64. That is not what that statement in Brantigan says, nor is that what Brantigan teaches—quite the opposite.

Prior art patents "must be considered in [their] entirety, *i.e.*, as a *whole*." *Panduit Corp.*, 810 F.2d at 1568 (original emphasis). As a whole, Brantigan's specification and claims repeatedly and specifically explain that its implants must be recessed within the vertebrae to sit on the endplate portion of the vertebra—*which, as a matter of anatomy, is substantially shorter than the full width of a vertebra. See Statement of the Case* §I.A, *supra*; A2790; A2626-28. Brantigan's implants are designed that way for two reasons.

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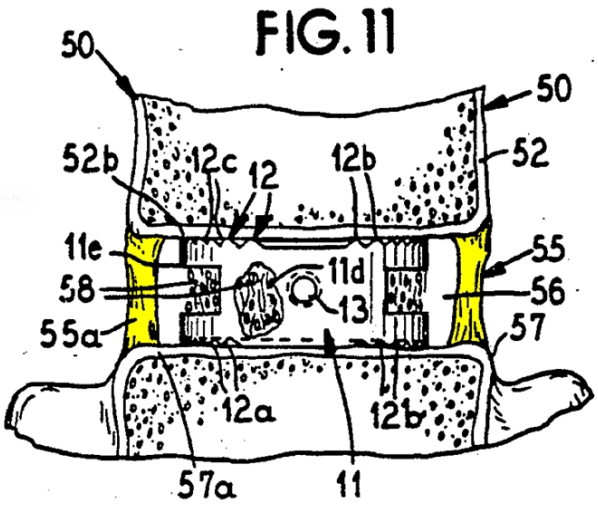
adequately "refute the prima facie showing" of obviousness. *See, e.g.*, A18, A20; A62; A63. But the "prima facie" case of obviousness must be made in the petition. *See Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012) (a reply first raising "evidence necessary to make out a *prima facie* case for patentability or unpatentability" will "not be considered and may be returned"). When an argument is first made in a petitioner's reply brief, the patent owner is unable to respond. The Board cannot fault Warsaw for not "refuting" an argument before it was made.

The first is to maximize contact with the vascularized (filled with blood vessels) area of the vertebral body—which no one disputes is the endplate—to promote tissue growth. Indeed, the patent teaches that "[t]he *periphery* of the oval ring is grooved to accommodate ingrowth of blood capillaries," A511(2:14-15)—*i.e.*, the whole implant, including the "periphery" should be inside the endplate region of the vertebral body. The second is to promote stability. The Brantigan specification explains that its implants "bottom out on [the] adjacent vertebral end faces," with the grooves on the periphery "gripping the vertebrae to resist expulsion" A511(2:59)-A512(3:1). Relatedly, the implant is sized to fit the endplate so that ligaments do not have to be cut and can instead act like "strut[s]," offering more stability. A513(6:25-28). Figure 11 shows implants seated on the vertebral endplates at the center of the vertebrae. A509-10.



(ligaments highlighted)

Brantigan claim 1 likewise illustrates that Brantigan's implants do not extend beyond the endplate. It recites implants that "conform[] in shape and size with hard *end plates* of vertebrae on which [they are] to be seated," and have "peaks to bite into the *end plates* of adjoining vertebrae." A514(7:30-38).[5]

Expert testimony further showed that Brantigan's implants are not designed to substantially span the full width of the adjacent vertebra. Dr. Brantigan himself, NuVasive's retained witness, A3153, testified under oath in related proceedings that Brantigan '327 does *not* disclose implants that extend beyond the vertebral endplates and onto the apophyseal ring. A3139(1495:7-18); A4467-68. Dr. van Dam, NuVasive's expert in district court, testified to the same point. A1455-56(1794:24–1795:4); A1273 ¶69.

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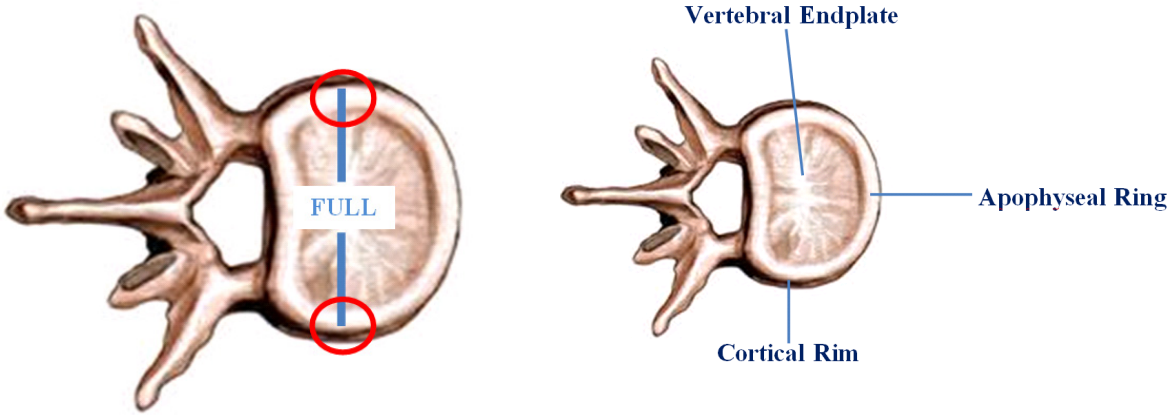
[5] In contrast to Brantigan, the '997 patent teaches a fundamentally different approach to the design and placement of an implant. It teaches that, because the implant is inserted from the side, it can be made longer and made to cover a greater portion of the width of the vertebra. *Statement of the Case §I.D, supra*; A107(11:3–8). That, in turn, allows for a greater area of contact between the implant and the vertebra, which provides stability and promotes ingrowth. A1249-50 ¶44; A112(21:33–38); A112(21:33-38); A103(3:18-30). Thus, as Dr. Sachs explained, the implant required by the claims would reach beyond the endplate and utilize the apophyseal ring. A2619-21.

An implant, as disclosed in Brantigan, that spans *only* the endplate, and does not extend onto the apophyseal ring, *cannot be substantially the full width of that vertebra*. *See* A1240-A1242 ¶29; A2619:13-2620:10; A2620:19-23. That is because the endplate is surrounded by the apophyseal ring of a vertebra, which occupies more than an insubstantial portion of the width of the vertebra.



That should have been the end of the matter.

The PTAB's conclusion that Brantigan teaches an implant sized to span substantially the full transverse width of adjacent vertebrae depends on its fundamental misunderstanding of the statement that the Brantigan implant is "generally shaped and sized to conform with the disc space." A16; A20; A61; A63. The PTAB read that to mean such an implant must necessarily be substantially the full width. But, that statement merely

explains that Brantigan's implants can be placed in the disc space without drilling or cutting into the vertebrae.

As Brantigan stated explicitly, the disclosed implants improve on the prior art because they do not require "cutting grooves or channels in the vertebrae." A511(1:44-46). Brantigan cites specific prior patents, and explains that they disclose implants "bottomed in channels or grooves of adjoining vertebrae," A511(1:40-41), which must be drilled or cut into the vertebrae. Brantigan then explains that "[t]he present invention now further improves this art … *without cutting* grooves or channels in the vertebrae." A511(1:44-47). Instead of cutting the patient's vertebrae and discs to conform with an implant, Brantigan takes the opposite approach and discloses implants that are "generally shaped and sized to conform with the disc space between adjoining vertebrae." A512(4:5-8). Thus, Brantigan discloses implants that can be stacked to a desired height, and that rely on teeth rather than screw threads so that they can be placed rather than drilled into the disc space. *See, e.g.*, A507(abstract), A511(1:14-29), *Statement of the Case § I.C.2, supra*.

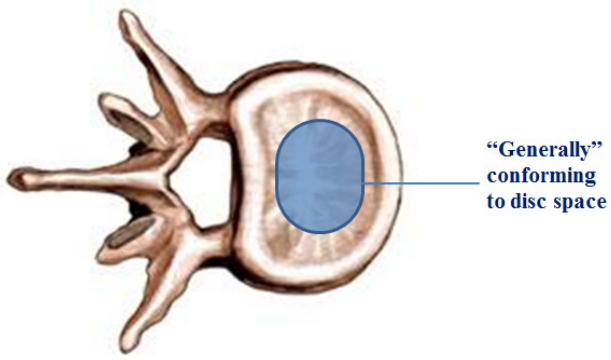
The Board's stretching of the lone statement that Brantigan's implants are "sized to conform with the disc space," to encompass the

limitations of the '997 patent, is unsupported[6] and inconsistent with Brantigan's repeated teaching that its implant is recessed on the endplate (*see supra pp.* 61-64; *Statement of the Case §I.C.2*)—which as a matter of anatomy cannot be substantially the full transverse width. It also simply makes no sense.

The fact that an implant is designed to fit the disc space does not reveal what all of its dimensions are, much less whether it substantially spans the full transverse width of the vertebrae adjacent to the disc space. To use a simple example, a child's crayon is sized and shaped to conform with the box its comes in, but that does not mean that a crayon substantially spans the width of the box—indeed, it does not. So too with Brantigan. Were there any doubt, Brantigan itself makes clear that its implants are not the same size as the entire intervertebral space in which they are recessed; rather, they are only sized "in the same ratio as normal vertebral bodies." A511(1:21). An implant whose periphery contacts the

[6] Brantigan and McAfee registered their agreement with NuVasive's argument, A2848-49, A2787, but to repeat an argument is not to support it, and certainly not to provide "substantial evidence of invalidity." *Koito Mfg.*, 381 F.3d at 1152.

endplate and whose dimensions are in the same ratio as normal vertebral bodies necessarily sits within the endplate.



Indeed, Dr. Sachs testified that a person of ordinary skill would understand that an implant that "would be short or less than the apophyseal ring and sit on the ... cortical end plate or somewhere in between"—*i.e.*, the Brantigan implant—would not "meet that limitation." A2621-22; *see also* A2620 ("Q. … So referring to those claims, 1, 9, and 17, is it your opinion that those claims require an implant to rest on the aphophyseal ring? A. At minimum, the aphophyseal ring, yes, that's my opinion."). Consistent with Sachs's testimony and the Brantigan patent's disclosure, Warsaw argued explicitly that "[t]he implants of the claimed methods are sized to rest on the apophyseal ring." A1169; A6008. The Board, however, either ignored or misunderstood Dr. Sachs's testimony and Warsaw's argument, as its final written decision inexplicably states: "Dr. Sachs does not appear to provide testimony supporting Patent Owner's implied contention

that one of ordinary skill in the art would have considered the term 'occupying substantially the full transverse width of the vertebral body,' as recited in claim 17, to mean 'occupying no more than the width of the vertebral endplate' or 'occupying (or not occupying) any portion of the apophyseal ring.'" A18 (claim 17); A61-62 (claim 1). The Board, thus, did not weigh Dr. Sachs' testimony, it denied that the testimony existed. The Board also asserted that "Patent Owner does not demonstrate that claim 17 requires that the implant includes 'the entire vertebral body.'" A17 (claim 17); A60-61 (claim 1). That is a *non-sequitur*. The question is whether the implant substantially spans the full transverse width of the vertebral body.

Following its misapprehension or disregard of the evidence, the Board stated that "Patent Owner does not show that claim 17 also recites an implant being sized to extend onto the apophyseal ring of the vertebral body or an implant being sized to extend beyond a central region of a vertebral body." A17 (claim 17); A60-61 (same, claim 1). The Board apparently misapprehended that Warsaw proved precisely that. An implant that only spans the endplate (which is all Brantigan discloses) *cannot* be substantially the full width of the vertebrae because the

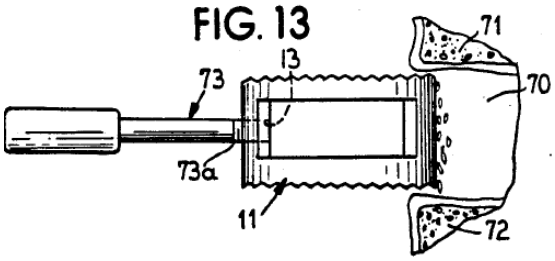
apophyseal ring itself occupies more than an insubstantial portion of the width of the vertebrae. Accordingly, the Board's finding that Brantigan discloses an implant with a length that spans substantially the full transverse width of adjacent vertebral bodies is not supported by substantial evidence and the obviousness determination must be reversed.

2. Brantigan Does Not Disclose An Implant With A "Length" Substantially The Full Transverse Width Of A Vertebra.

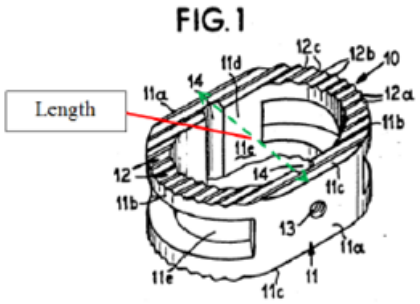
Even if Brantigan is viewed as disclosing an implant with *some* dimension that was substantially the full transverse width of a vertebra, that dimension cannot possibly be the "*length*" as the claims use that term. Claims 1 and 17 define "length" as the dimension between "an insertion end … and a trailing end":

> inserting ... an interbody intraspinal implant ... having an ***insertion end*** for insertion first into the laterally facing opening and ***a trailing end*** and a ***length therebetween***, the ***length of said implant being sized to occupy substantially the full transverse width*** of the vertebral bodies of the two adjacent vertebrae

A114(26:8-13) Brantigan's leading to trailing "length" is illustrated below (depicting a side view of the implant being pushed in with an insertion rod, and a top view of a Brantigan implant):



A510



A508 (as annotated at A1309)

Thus, to determine whether the prior art discloses the claimed limitation, the Board was required to (1) determine the direction of insertion of the disclosed Brantigan implant, and then examine (2) whether the "*length*" of a Brantigan implant (from leading to trailing end) is substantially the full transverse width of the vertebrae. The Board explicitly refused to undertake that analysis:

> Patent Owner argues that Brantigan discloses "an anterior approach to the spine," as opposed to a lateral approach. As previously discussed, Jacobson discloses or suggests this feature. We need not determine whether one of ordinary skill in the art would have understood Brantigan to also disclose this feature.

(A21 (citations omitted).) That was error. The Board only considered whether Brantigan's implant had *some dimension* that could occupy substantially the full transverse width of adjacent vertebral bodies. But having a *width* that is substantially the full width of the vertebrae is not the same as having a *length* of that dimension.

The Board's error permeates its opinions. It states "claim 17 recites *an implant being sized* to occupy substantially the full transverse width of the vertebral body," but that reads the "length" limitations out of the claim. A17; A60 (same, claim 1); *see, e.g.*, A16 (heading titled "Brantigan - '*implant* being sized to occupy substantially the full transverse widths of the vertebral bodies'"); A59 (same), A16–A17 ("Patent Owner argues that Brantigan fails to disclose *an implant* that includes (or overlaps) the apophyseal ring of a vertebral body..."); A60 (same), A20 ("[I]t would have been obvious to one of ordinary skill in the art to have provided *an implant* sized to occupy ..."); A63 (same), A20 ("Brantigan discloses that *the implant* is 'sized to conform with the disc space'"); A64 (same).

That is no mere semantic distinction. The "length" limitations claim Dr. Michelson's insights about how a laterally-inserted implant can be designed differently from prior art implants. *Statement of the Case §I.D, supra*. The Brantigan implants were not designed or intended for lateral implantation. A1298-1305. The disclosure repeatedly describes anterior or posterior implantation, and says *nothing* about implantation from the side. *See, e.g.*, A511(1:44-47) ("especially well suited for anterior" implantation); A511(2:8-11) (modular design facilitates implantation from

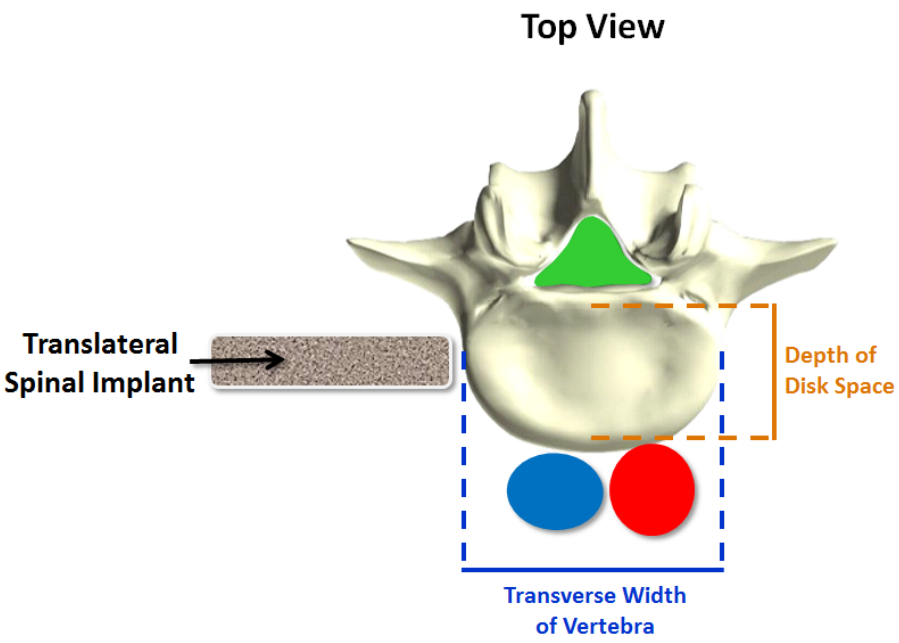
the back). NuVasive has pointed to Brantigan's use of the word "lateral," and to Brantigan's Figure 10, but those contentions are unsupportable. As the district court concluded in related litigation, Brantigan's reference to "lateral" refers to insertion from the front or back, but to the side of the mid-line. A891 ¶¶47-48 (district court). Brantigan and McAfee admitted as much. A1433-34 (Brantigan); McAfee (A1373-74). Sachs explained how Brantigan's use of "lateral" was consistent with how others used the term at the time, A1298, with other publications and patents by Brantigan, A1299-1300, and with Brantigan's trial testimony. A1300-01. Further, Figure 10 is the same implant "plug 11," depicted in figures 1, 4, 8, 10, and 11, which the specification explicitly states is to be inserted from the front. A1303. Brantigan plainly does not disclose insertion from the side of the patient, and the Board's reading of Brantigan thus reflects a fundamental misunderstanding of the claims and disclosure.

Intervertebral implants designed for lateral insertion did not exist at the time of Michelson's invention. A1250 ¶45; *Warsaw*, 778 F.3d at 1370. The Board did not find to the contrary. Nor was there evidence in the record supporting the notion that a skilled artisan would have been motivated to modify the Brantigan implant so its width could become its

length. The issue is not simply one of reorienting an implant: as noted above, spinal implants have complex surface characteristics designed to make them suitable for particular placement in the spine. A3280-81. The Board attempted to sidestep the issue, stating "Jacobson discloses or suggests" a lateral approach. A21. But that does not answer the question whether a Brantigan implant was even capable of being inserted laterally using the '997 method.

3. Brantigan Does Not Disclose Implants With A Length—Or Any Dimension—"Greater Than The Depth Of The Disc Space."

Regardless of whether Brantigan discloses an implant with a length substantially the full transverse width of a vertebra, it does not disclose an implant with a length "greater than the depth of the disc space." That is an important aspect of the claims: an implant whose length (from insertion end to trailing end) is "greater than the depth of the disc space" can *only be laterally inserted*.



As Warsaw explained below, an implant inserted from the front or back, whose length (from insertion end to trailing end) is "greater than the depth of the disc space," would protrude from the spinal column and contact the spinal cord or major blood vessels. *See, e.g.*, A686-87; A1308-10; A4809. An implant capable of traditional front/back insertion, thus, cannot satisfy this claim limitation.

"Differences" between the prior art and claimed invention, 35 U.S.C. § 103, are part of the obviousness analysis and must be explained. *KSR*, 550 U.S. at 417-18. Teaching away has always been, and remains, relevant. *United States v. Adams*, 383 U.S. 39, 51-52 (1966); *Institut Pasteur v. Focarino*, 738 F.3d 1337, 1345 (Fed. Cir. 2013) (teaching away "counts significantly against finding a motivation" to combine prior art);

DePuy Spine Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314, 1326-27 (Fed. Cir. 2009). For NuVasive to show—and for the Board to declare—that a skilled artisan would arrive at the implant required by the claims from the fundamentally opposite teachings of Brantigan requires some "articulated reasoning with some rational underpinning." *KSR*, 550 U.S. at 417-18. The Board provided no such reasoning, and none exists in the record.

The Board made no specific findings about whether the prior art disclosed that aspect of the claimed length. The Board relied generally on Brantigan's statement that its implants are "sized to conform with the disc space," A20. Brantigan, however, makes clear throughout that its implants *are* capable of being inserted from the front or the back, and promotes that versatility as an advantage. *See, e.g.*, A511(2:8-11); A511(2:12-14); A511(1:44-47). The disclosed Brantigan implants thus *necessarily cannot* have a "length … greater than the depth of the disc space."

That point should have been particularly clear to the Board from Brantigan's disclosure of an implant that "can be rotated or reversed and still fit the vertebrae." A511(2:24-25). But the Board misunderstood the

issue. Dr. Sachs explained that an implant capable of being rotated in the disc space *during* "the surgical procedure," must be shorter than the depth of the disc space in every dimension and well inside the apophyseal ring. A1308 ¶113. Where an implant can be "rotated or reversed" or inserted in any direction and "still fit the vertebrae," *every* dimension of that implant is necessarily *shorter* than the depth of the disc space. Otherwise, rotating the implant would risk contacting the spinal cord behind the disc space or the major blood vessels in front, paralyzing or killing the patient. *Id.*

The Board's response to this simple point is deeply confused. The Board stated that it agreed with NuVasive "that one of ordinary skill in the art would have understood not to remove an implant once already inserted because doing so would not have permitted the implant to have provided the support desired or to have fused with adjacent vertebrae, as Brantigan discloses" and that "Brantigan may be selected to be inserted in any desired orientation (*i.e.*, 'rotated or reversed' *prior to* insertion so that the implant will 'still fit the vertebrae')." A20. But Warsaw never argued that Brantigan suggested rotating the implant inside the patient's body *after* surgery. Rather, Warsaw's point was that an implant that can be rotated or reversed to "simplif[y] the surgical procedure," A511(2:24)

cannot be longer than the depth of the disc space. A685-86; A1200; A1308 ¶113; A4809.

Brantigan's disclosure of implants that can be rotated or reversed thus *teaches away* from the '997 patent. The '997 patent teaches the opposite: implants designed to be inserted laterally can be designed differently, but must be inserted along a specific dimension. Lateral-specific implants *cannot* be "rotated," nor inserted from different directions, but they can be made oversized, including to have a "length … greater than the depth of the disc space." The Board's contrary conclusions fundamentally misread Brantigan and cannot be squared with the record or with Brantigan's disclosure.

* * *

Because Brantigan does not disclose an implant that meets *any* (much less all) of the implant length limitations required by claims 1-8 and 17-23, the Board's conclusion that these claims merely disclose combinations of known elements is not supported by substantial evidence. And the Board made no findings that a skilled artisan would have found it obvious to modify the Brantigan implant in any manner, much less a manner that would meet the claim limitations. Bereft of its factual

underpinnings, the Board's legal conclusion that claims 1-8 and 17-23 are unpatentable must be reversed.

B. The Board's Findings About The Asserted Combinations Are Insufficient As A Matter of Law To Render Claims 1-8 and 17-23 Obvious.

Even if one accepts the Board's factual findings regarding Brantigan's disclosure, the obviousness ruling must still be reversed for the further reason that no analysis or evidence offered by the Board (or NuVasive) suggests any reason to modify Brantigan into the oversized lateral implant required by the claims, much less any reason why a person of skill in the art would combine Jacobson, Leu, and Brantigan to arrive at the claimed inventions. The Board's decision depends on precisely the sort of hindsight-based reasoning and "jigsaw puzzle" approach to obviousness that this Court's precedents foreclose.

KSR clarified that the obviousness inquiry is "expansive and flexible," 550 U.S. at 415, and not conducive to "[r]igid preventative rules that deny factfinders recourse to common sense." *Id.* at 421. *KSR* makes equally clear, however, that obviousness is not simply multi-reference anticipation. *Id.* at 418 ("a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art"). Rather, a patent challenger must show a *reason* for modifying or combining the prior art to arrive at the claimed invention. *Id.* at 417-18 ("[T]his analysis should be made explicit … 'rejections on obviousness grounds cannot be sustained by mere conclusory statements … there must be some articulated reasoning with some rational underpinning.'") (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). That requirement of a reason or motivation is critical to avoiding "hindsight bias and … arguments reliant on *ex post* reasoning." *Id.* at 421. The reason or motivation need not be an explicit disclosure, *id.* at 402, but it *cannot* come from hindsight or *ipse dixit* argumentation, *id.* at 415, 418, nor can it be left out of the analysis altogether. *Id.* at 418.

Obviousness thus cannot be approached like a "jigsaw" puzzle, where the patent challenger locates each claim element in different references and simply asserts that a person of skill could have combined the references to arrive at the claimed invention. In *InTouch*, this Court reversed an obviousness judgment predicated on such an analysis. The patent challenger's expert "opined that all of the elements of the claims disparately existed in the prior art" and that "the references were like separate pieces of a simple jigsaw puzzle." 751 F.3d at 1348-49. The

expert failed, however, to "provide the glue to combine these references," offering at most "a belief that one of ordinary skill in the art *could* combine these references, not that they *would* have been motivated to do so." *Id.* at 1348-49. 1352 (original emphasis); *see also Leo,* 726 F.3d at 1354; *Plantronics*, 724 F.3d at 1354; *Genetics Inst.*, 655 F.3d at 1304-05.

That "jigsaw" approach is precisely the type of proof NuVasive offered for claims 1-8 and 17-23, and precisely the mode of analysis the Board applied to invalidate those claims. In sections titled "*Jacobson—'lateral'," "Brantigan—'implant…,'" "Leu—'interbody intraspinal implant,'"* and *"Elongated portion,"* the Board marches through prior art to locate individual claim elements. A7-23 (claims 17-23); A50-66 (claims 1-8). Then, in a conclusory section labeled "*Jacobson, Leu, Brantigan—combinability*," A23-25; A66-68, the Board simply declares its agreement with NuVasive. The *entire* affirmative portion of the Board's analysis in that section consists of the following five sentences, which, again, simply march through the prior art and declare the conclusion of obviousness as a matter of *ipse dixit*:

> Jacobson discloses advancing instruments laterally into the disc space to perform a "fusion" procedure. Ex. 1004, 5:1–4, 6:11–13. Leu discloses fusion of the lumbar spine by introducing an "interbody graft" into the disc space. Ex. 1005,

> p. 603. Brantigan, like Leu, discloses "prosthetic implant devices" that are "suitable for … lateral placement in any area of the spine." Ex. 1006, 2:56–58. We agree with Petitioner that the combination of the known element of performing a spinal fusion procedure by laterally advancing instruments into the disc space (Jacobson) with the known element of using an "interbody graft" in a spinal fusion procedure (Leu and Brantigan) would have resulted in no more than the predictable and expected result of performing a spinal fusion procedure (Jacobson) that includes inserting an implant into a disc space (Leu or Brantigan). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007).

A23-24 (claims 17-23); A66-67 (same, claims 1-8). Even setting aside that that analysis entirely ignores the critical "length" limitations, this is a classic example of the sort of hindsight-based, "jigsaw" approach to obviousness that this Court has repeatedly reversed and cautioned against. To declare that combining and modifying the prior art would yield "predictable and expected result[s]" is to fail to provide any *reason* why a person of skill would have done so in the first place. The remainder of the Board's "combinability" analysis consists of nothing more than statements that the Board was "not persuaded" by Warsaw's arguments, A24-25, A67-68, seemingly ignoring that NuVasive bore the burden of proof of obviousness. 35 U.S.C. § 316(e).

The Board did not supply the necessary explanation or evidence for combining Jacobson, Leu, and Brantigan because it could not. The '997 patent does not broadly claim the idea of making incisions and inserting spinal implants from the side. Yet, the Board treated the patent as if it did—looking only for references that disclosed lateral incisions and spinal implants and declaring that a person of skill in the art would have combined those references:

> [T]he known element of performing a spinal fusion procedure by laterally advancing instruments into the disc space (Jacobson) with the known element of using an "interbody graft" in a spinal fusion procedure (Leu and Brantigan) would have resulted in no more than the predictable and expected result of performing a spinal fusion procedure (Jacobson) that includes inserting an implant into a disc space (Leu or Brantigan).

A23-24 (claims 17-23); A66-67 (same, claims 1-8)

The '997 patent, however, describes and claims specific methods, instruments, and implants, specifically designed to facilitate spinal fusion performed directly from the side of the spinal column. A112-15. The Board gives no reasoning, and cites no evidence, for why a skilled artisan would divine the '997 patent's teachings from Jacobson, Leu, and Brantigan.

Jacobson says nothing at all about designing or using spinal *implants*. A1319-20. Indeed, the Board correctly rejected NuVasive's arguments to the effect that Jacobson discloses the use of implants. A15. Jacobson discloses percutaneous needle puncture) surgery, A477 (Abstract), done as non-invasively as possible. A487(5:51-54). Jacobson mentions "fusion" once in passing, A487(6:13) does not discuss implants, and does not discuss or suggest the use of its needle-puncture methods in conjunction with the insertion of a large structural implant meant to replace an entire disc. A1321. Indeed, Jacobson teaches to anchor its working cannula by sticking wires into the disc capsule, which would obstruct the insertion of an implant. A488(7:3-13). The Board points to nothing that would make it obvious to a skilled artisan to take that limited surgical procedure and assume it could be modified to insert a large implant.

Leu, similarly teaches pushing a soft "graft conglomerate" into the intervertebral space through a small 7 mm diameter cannula. *See* A1293. The Board's discussion of Leu references a paragraph of Dr. McAfee's reply declaration. A22 (citing A2766-67 ¶57); A65 (citing A7577-78 ¶57). In that declaration, however, from the premise that "spinal surgeons of

ordinary skill" used "non-bone" implants, McAfee concludes without explanation that "a person of ordinary skill would have been prompted … to employ an implant structure *having a size/structure suggested by Brantigan* in the resulting surgical method of Jacobson in view of Leu." A2767 (original emphasis); A7578 (same). It is far from self-evident that knowledge to make spinal implants out of "non-bone" would lead a person of skill in the art to combine three disparate references in specific ways to arrive at the claimed invention. McAfee does not explain that leap of logic; he simply asserts it. As a matter of law, that is not sufficient. "General and conclusory testimony … does not suffice as substantial evidence of invalidity." *Koito Mfg.*, 381 F.3d at 1152.

The Brantigan implants, moreover, were based on a fundamentally different design philosophy from the '997 patent. Brantigan taught the advantages of contact between the implant and the vertebral endplate (stability and ingrowth); the '997 patent taught the advantages of contact with the area beyond the vertebral endplate. *See* A100 (Fig. 30); A107 (11:3-12); A112 (21:4-11, 21:33-38). Brantigan taught that the oval shape and modular design of the implants provided versatility, so that the implants could be inserted in different ways and could "be rotated or

reversed and still fit the vertebrae," A511(2:24-25); the '997 patent teaches the exact opposite—*sacrificing* versatility to realize advantages made possible by designing an implant *only* for lateral insertion. *Statement of the Case §I.D.*

These fundamental "differences" between the prior art and claimed invention must be explained in an obviousness analysis. 35 U.S.C. § 103; *KSR*, 550 U.S. at 417-18. They cannot simply be ignored or dismissed with hindsight by assuming the conclusion of obviousness, as the Board did here. For NuVasive to show—and for the Board to declare—a skilled artisan would derive the implant, methods, and instrumentation of the '997 patent claims from the disparate teachings of Jacobson, Leu, and Brantigan, requires some "articulated reasoning with some rational underpinning." *KSR*, 550 U.S. at 417-18. But again, the Board provided no such reasoning, nor does any exist in the record. Nothing argued or cited by NuVasive or the Board suggests modifying Brantigan into the oversized implant required by the claims, nor combining Jacobson, Leu, and Brantigan. Because NuVasive's proof and the Board's analysis fall short of what precedent requires, the obviousness ruling must be reversed.

IV. The Board Erred in Finding Claims 17-23 Unpatentable For the Further Reason That Jacobson Does Not Disclose Positioning Elongated Portions Over Adjacent Vertebrae.

The Board's decision regarding claims 17–23 should be reversed for an additional, independent reason: There is no substantial evidence supporting the Board's conclusion that Jacobson discloses a surgical instrument with "elongated portions" positioned so that at least part of one portion is "over one of the two adjacent vertebrae and at least part of another … elongated portion[] is over the other of the two adjacent vertebrae." A114(25:65–26:2).

NuVasive argued, and the Board accepted, that Jacobson's "anchor wires" met this limitation. A23. But they clearly cannot. Jacobson teaches advancing these wires "into the disc capsule" itself, to anchor a cannula into the disc. A488(7:3–13). Figure 6 of Jacobson (A480) depicts these anchor wires (14):

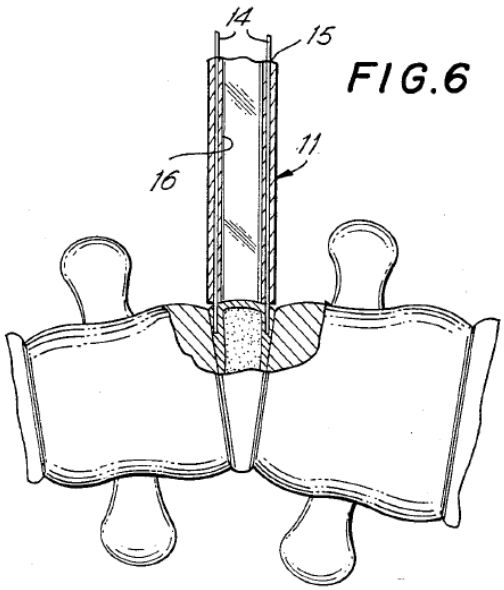


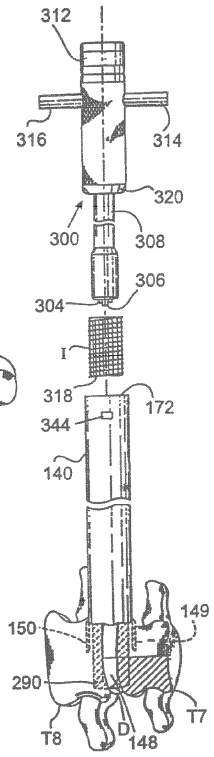
FIG.6

As Jacobson's written description and drawings demonstrate, because these anchor wires are over the disc space, they are not over (or even partly over) the adjacent vertebrae. A479-80 (Figs. 5-6); A488(7:3-13). Accordingly, there is *no evidence*, let alone substantial evidence, supporting the Board's determination that Jacobson's anchor wires disclose this method step.

Nor did the Board make any findings to support the notion that it would be obvious to use a surgical instrument that, instead of just anchoring itself to the disc tissue, was positioned above the adjacent vertebrae themselves. That limitation is not superfluous. Positioning the elongated members in this way creates a clear surgical path to the entire disc space for subsequent insertion of an implant—not just part of the disc space, as

Jacobson discloses. *See* A96-98(Figs. 18–20, 22) (showing prongs on extended outer sleeve, as shown below).

FIG. 18



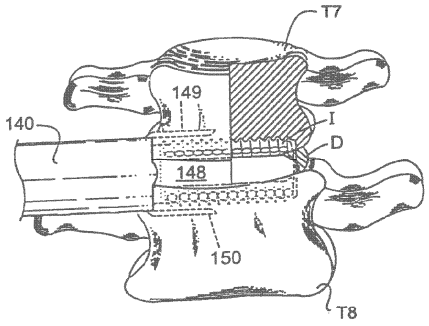
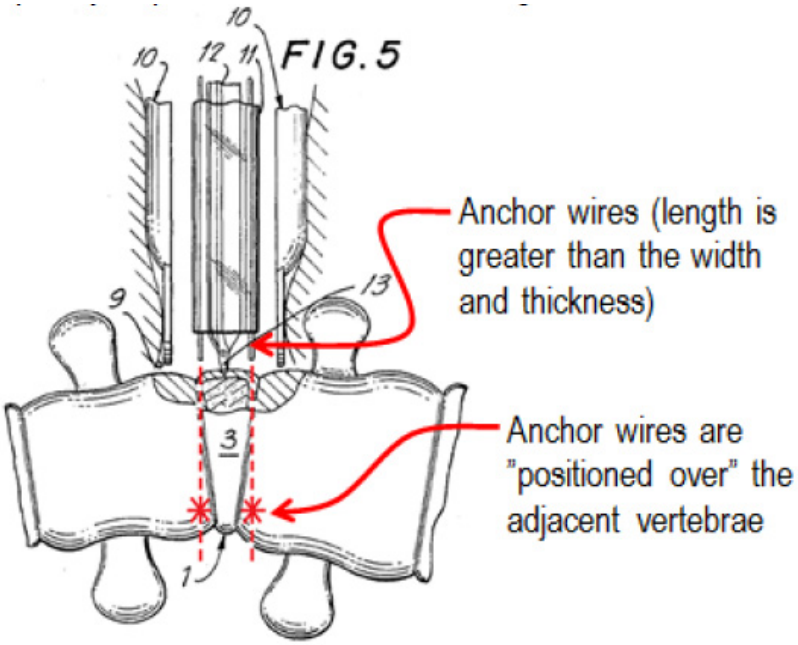


FIG. 19

To the extent the Board adopted NuVasive's argument and implicitly construed "positioning … over" to include all items indirectly below the elongated portions in the same vertical plane, rather than the surface directly beneath it, such a claim construction is unreasonable and inconsistent with the '997 specification. *First*, the '997 specification only describes and illustrates elongated portions that are spaced apart further than the height of the disc space. *See* A91-A94(Figs. 7, 9–13), A95-

A98(Figs. 16–20, 22). This spacing allows full access to the height of a disc space for the insertion of an implant. *Id.* The same would not be true if positioning over the disc space was sufficient to meet the claim limitation, on the theory that vertebrae are buried underneath.

Indeed, the illustrations in NuVasive's petition below (apparently persuasive to the Board) show that the anchor wires limit the size of the opening for the insertion of an implant between the elongated portions, contrary to what the '997 Patent teaches (A268):



Second, this construction is inconsistent with the plain language of the term "positioning … over," which suggests an unobstructed path between two objects. The prongs in Jacobson are not "positioned over" adjacent vertebral bodies just as they are not "positioned over" the

operating table, "positioned over" the operating room floor, or "positioned over" the hospital basement below the operating room. NuVasive's position is analogous to describing a plane flying over the ocean as "positioned over" land because there is land beneath the ocean.

Because Jacobson does not disclose a distinct element of claims 17-23, and because the Board did not make any findings that a person of skill in the art would find it obvious to modify Jacobson, or any other prior art, to meet that limitation, the Board's finding that claims 17-23 are unpatentable must be reversed for this additional reason.

CONCLUSION

The Board's rulings that claims 9-16 and 24-30 are patentable should be affirmed; its rulings that claims 1-8 and 17-23 are unpatentable should be reversed.

May 29, 2015

Respectfully submitted,

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ADDENDUM

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Paper 65
Date: July 10, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

WARSAW ORTHOPEDIC, INC.,
Patent Owner.

Case IPR2013-00206
Patent 8,251,997 B2

Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges.*

SIU, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

NuVasive, Inc. ("Petitioner") filed a petition (Paper 5) ("Pet.") seeking *inter partes* review of claims 9–30 of U.S. Patent No. 8,251,997 B2 (Ex. 1002, "the '997 patent") pursuant to 35 U.S.C. §§ 311–319.[1] On

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[1] We cite to Petitioner's Corrected Petition for *Inter Partes* Review of United States Patent No. 8,251,997 B2, filed April 3, 2013. Paper 5.

September 23, 2013, the Board instituted an *inter partes* review of all claims on six grounds of unpatentability (Paper 17) ("Dec. on Inst.").

Subsequent to institution, Warsaw Orthopedic, Inc. ("Patent Owner") filed a Patent Owner Response (Paper 32) ("PO Resp."), and Petitioner filed a Reply (Paper 43) ("Pet. Reply"). Patent Owner also filed a Motion to Exclude Evidence. Paper 53. Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 59) ("Opp."), and Patent Owner filed a Reply (Paper 60) ("PO Reply"). An Oral Hearing was conducted on June 5, 2014, pursuant to a request for oral hearing filed by Petitioner (Paper 52) and Patent Owner (Paper 54).

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 17–23 of the '997 patent are unpatentable, but has not shown by a preponderance of the evidence that claims 9–16 and 24–30 of the '997 patent are unpatentable.

A. The '997 Patent (Ex. 1002) [2]

The '997 patent describes methods and instrumentation for performing surgery on the spine along its lateral aspect. Ex. 1002, 3:34–36; Figs. 1 and 2. Guide pin 30 is inserted from the lateral approach to the spine and functions as a guide post for distractor 100 that is placed over the guide pin and inserted into the disc space to distract the vertebrae. Ex. 1002, 8:52–53; 9:12–14; 10:10–12; Figs. 2–5. Extended outer sleeve 140 is placed over the distractor and inserted into the disc space. Ex. 1002, 10:22–25, Fig. 12.

[2] We refer to Ex. 1002 submitted by Petitioner and dated March 22, 2013.

A spinal implant I is introduced through the extended outer sleeve and installed across the disc space. Ex. 1002, 15:64–65; 16:24–26; Figs. 19, 22, 23, 30, and 30A.

B. Illustrative Claim

Claim 9 is illustrative of the claimed subject matter of the '997 patent, and is reproduced as follows:

> 9. A method comprising:
>
> making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;
>
> advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;
>
> advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

positioning a single elongated portion removably attached to said distal end of said third surgical instrument over the disc space, said single elongated portion having a length, a thickness, and a width, the length of said single elongated portion being greater than the width and the thickness of said single elongated portion, the width of said single elongated portion being greater than the thickness of said single elongated portion, said single elongated portion being tapered to facilitate entry between the vertebral bodies of the two adjacent vertebrae;

inserting said single elongated portion into the disc space with the width of said single elongated portion being oriented along a height of the disc space; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

C. Cited Prior Art

The pending grounds of unpatentabililty in this *inter partes* review are based on the following prior art:

Jacobson	US 4,545,374	Oct. 8, 1985	(Ex. 1004)
Brantigan	US 5,192,327	Mar. 9, 1993	(Ex. 1006)
Frey	US 4,917,704	Apr. 17, 1990	(Ex. 1007)
Michelson ’247	US 5,015,247	May 14, 1991	(Ex. 1008)
McAfee	US 5,569,290	Oct. 29, 1996	(Ex. 1009)

Hansjörg F. Leu and Adam Schreiber; *Percutaneous Fusion of the Lumbar Spine: A Promising Technique*, 6(3) SPINE: STATE OF THE ART REVIEWS 593 (Sept. 1992) (Ex. 1005, “Leu”).

D. Pending Grounds of Unpatentability

This *inter partes* review involves the following asserted grounds of unpatentability:

Reference(s)	**Basis**	**Claims challenged**
Jacobson, Leu, McAfee, and Michelson ’247	§103	9 and 16
Jacobson, Leu, McAfee, Michelson ’247, and Frey	§103	10–15
Jacobson, Leu, and Brantigan	§103	17 and 23
Jacobson, Leu, Brantigan, and Frey	§103	18–22
Jacobson, Leu, and Michelson ’247	§ 103	24 and 30
Jacobson, Leu, Michelson ’247, and Frey	§ 103	25–29

E. Claim Interpretation

The parties appear to agree with the interpretation of various claim terms of the '997 patent as described in the Decision on Institution with additions or modifications as set forth below. We incorporate our previous analysis for the non-disputed claim terms.

1. "a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes" (claim 9)

Patent Owner argues that an "axis lying in a coronal plane" should be construed as an axis that is lying in "a plane at right angles to a sagittal plane." PO Resp. 11. Petitioner does not contest Patent Owner's assertion that one of ordinary skill in the art would understand that a "coronal plane" would be oriented "at right angles to a sagittal plane." Pet. Reply 1. Thus, no further construction of this term is necessary.

2. "elongated portion" (claim 9)

Patent Owner argues that the term "elongated portion" should be broadly, but reasonably, construed as a portion in which "its length is *substantially* greater than its width." PO Resp. 12. Petitioner argues that "elongated" should be construed as a portion having a length greater than its width. Pet. Reply 1–2. As Petitioner points out, claim 9, for example, recites the "length of said single elongated portion being greater than the width . . . of said single elongated portion." Patent Owner does not show persuasively that the claims recite a requirement that the length of the elongated portion is "substantially" greater than the width of the elongated portion or that the Specification discloses such a requirement. Patent Owner

also does not provide a persuasive rationale as to why one of ordinary skill in the art would have assumed that the length of the elongated portion is "substantially" greater than the width of the elongated portion in view of the absence of the disputed qualifier in the claims and Specification.

We construe the elongated portion as having a length that is greater than the width of the elongated portion.

II. ANALYSIS

A. Grounds Based at Least in Part on Jacobson, Leu, and Brantigan (Claims 17–23)

Claim 17 recites a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae. Patent Owner contends that a path having an axis lying in a coronal plane, as recited in claim 17, must be a path that is "a direct or true lateral path to the spine." PO Resp. 11. Petitioner concurs. Pet. Reply 1.

Jacobson – "lateral"

Jacobson discloses a procedure in which "a cannula is passed laterally through the body," a needle that "is inserted laterally through the patient's side" that "may act as a guide member . . . for instruments that create the percutaneous body channel," a speculum that "is laterally inserted through body tissue" and is "used to create the lateral cavity through body tissue into which the cannula will be inserted." Ex. 1004, 5:1–2, 5:27–28, 5:49–51, 5:40–42, 8:53–55. Jacobson also provides drawings of the approach to the intervertebral space. The drawings depict a lateral approach to the intervertebral space, consistent with the textual description. Ex. 1004, Figs. 1–6.

Patent Owner argues that while Jacobson discloses accessing a disc space from a "lateral" aspect, the term "lateral" "has any number of meanings, including anterolateral, posterolateral, direct lateral, and lateral to the midline of the vertebral bodies" and that, despite Jacobson's disclosure of a "lateral" approach, Jacobson actually "discloses a posterolateral – not a direct lateral – approach to the spine." PO Resp. 19 (citing Ex. 2039, 37:25 – 39:1).

Petitioner provides testimony of Dr. Robert E. Jacobson to demonstrate what one of ordinary skill in the art would have understood the term "lateral" to mean in the context of performing a spinal fusion procedure. Ex. 1030 ¶ 5. Dr. Jacobson testifies that one of ordinary skill in the art would not have used (or understood) the term "direct lateral" but, instead, would have used the term "lateral" as Patent Owner uses the term in the present proceedings.[3] We credit Dr. Jacobson's testimony that one of ordinary skill in the art would have understood the term "lateral" to mean what it says (i.e., to mean "lateral"), at least because it would have been reasonable for one of ordinary skill in the art to have construed a term (i.e., "lateral") with a common, accepted definition. Patent Owner's observation that a construction of the term "lateral" that was in use at the time of the invention included a "direct lateral" approach (as understood in this proceeding) further supports Dr. Jacobson's testimony that one of ordinary skill in the art would have understood the term "lateral" to mean "direct

[3] Dr. Jacobson testifies that "the phrase 'direct lateral' was not a phrase that I used in the technical parlance of my profession . . . at that time I had never heard the phrase 'direct lateral' to describe a 90 degree lateral approach to the spine. Instead, . . . I (and others) simply used the term 'lateral' when referring to a 90 degree lateral approach to the spine." Ex. 1030 ¶5.

lateral," as that term is presently construed in the instant proceedings. Also, we note that claim 17 does not recite the term "direct lateral," and Patent Owner does not assert that the '997 patent specification discloses the term "direct lateral." The absence of the term "direct lateral" in the '997 patent further supports that one of ordinary skill in the art at the time of the invention would not have used (or understood) the term "direct lateral."

In addition to Jacobson's explicit disclosure of, for example, "laterally inserting a cannula," Jacobson discloses figures that illustrate what Patent Owner now refers to as a "direct lateral" approach (i.e., lateral insertion along a path having an axis lying in a coronal plane). Ex. 1004, 2:26–27, Figs. 3–8. We note that in each of the figures of Jacobson, the outer side periphery of the instrument(s) inserted "laterally" into the intervertebral space, as illustrated, are depicted by parallel lines that are oriented at 90 degrees from a horizontal surface. Based on the depiction of the outer side contours of the instrument(s) as being oriented 90 degrees from a horizontal surface, one of ordinary skill in the art would have understood that the instrument(s) are perpendicular to an underlying horizontal surface in the superior-inferior perspective (with respect to the orientation of the patient). More importantly, as the outer side contours of the instruments are parallel in these perspectives, one of ordinary skill in the art would have understood the instruments, as illustrated by Jacobson, to be perpendicular to an underlying horizontal surface in the medial-lateral perspective (with respect to the orientation of the patient – i.e., that the orientation of the instrument(s) is "direct lateral," as Patent Owner uses that phrase, and not "posterolateral" or "anterolateral"). That is true because, assuming the instrument(s) illustrated in Jacobson are cylindrical, if the instrument(s) were angled away

from the viewer, the outer side contours of the instrument(s) at the point of insertion into the intervertebral space would appear farther away from each other as compared to the outer side contours of the instrument(s) at the point farthest from the point of insertion into the intervertebral space (i.e., the proximal end of the instrument(s), which would be located farther away from the viewer). Likewise, if the instrument(s) were angled toward the viewer, the outer side contours of the instrument(s) at the point of insertion into the intervertebral space would appear closer to each other as compared to the outer side contours of the instrument(s) at the point farthest from the point of insertion into the intervertebral space (i.e., the proximal end of the instrument(s), which is located closer to the viewer).

Moreover, as Petitioner's declarant (Dr. Paul McAfee) points out, an anterior cross sectional view of the instrument(s) in-situ (i.e., Ex. 1004, Fig. 6) shows an even and symmetrical view of the instruments throughout the length of the instrument(s). *See, e.g.*, Ex. 1029 ¶ 38. Dr. McAfee's testimony further supports that Jacobson discloses that the instruments are inserted along a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae, as recited in claim 17 (i.e., the "direct lateral" approach as presently understood in the instant proceedings).

Patent Owner argues that the figures as disclosed by Jacobson "appear to show a direct lateral path," but "do not clearly show the surgical approach" because the figures "are merely two-dimensional depictions [that depict the same orientation]" and that "these figures [of Jacobson] could just as likely disclose a posterolateral or anterolateral approach to the spine." PO Resp. 23–24 (citing Ex. 2038 ¶ 81). Patent Owner does not explain

adequately, however, how the anterior view of instrument(s) illustrated in Jacobson, with parallel outer side contours as described above or the anterior cross-sectional view of the instrument(s) throughout the length of the instrument(s) as also described above (i.e., instrument(s) that are normal to an underlying horizontal surface), "could just as likely" illustrate instrument(s) that are angled with respect to an underlying horizontal surface. While Patent Owner also argues that "surgeons are trained to orient an instrument in a patient's body by taking images of the instrument from multiple angles," Patent Owner does not demonstrate persuasively that, even if surgeons are trained to take images at multiple angles, that Jacobson illustrates that the instrument(s) are angled (i.e., a posterolateral or anterolateral approach). PO Resp. 24 (citing Ex. 2038 ¶ 81).

Patent Owner argues that Jacobson "discloses a method of performing percutaneous discectomy that implicates anatomical structures such as the spinal nerves and nerve root – structures that are encountered during a posterolateral (not direct lateral) approach to the spine" and a "stimulator [that] will cause motion in one of the patient's legs if it makes nerve contact [and that motor nerves are implicated only in a posterolateral approach.]" PO Resp. 19–20 (citing Ex. 2038 ¶¶ 76–77; Ex. 1004, 6:38–40). As Patent Owner indicates, Jacobson discloses "[t]o prevent nerve damage, a nerve stimulator . . . may be attached or passed down into the cannula or trocar to indicate if either instrument is hitting one of the spinal nerves or exiting nerve branches." Ex. 1004, 6:32–38. It is not disputed that Jacobson discloses a "lateral approach" that includes a "direct lateral" approach, as construed in the instant proceedings (see discussion above). Also, as described above, Jacobson discloses illustrations of a spinal fusion

procedure in which instruments are inserted into an intervertebral space (i.e., a "direct lateral" approach as presently understood) while oriented normal to an underlying horizontal surface (i.e., having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae). Patent Owner does not demonstrate sufficiently how Jacobson's further disclosure of the possible use of a "nerve stimulator" that indicates if an attached instrument contacts a nerve means that Jacobson does not disclose or suggest a lateral approach. For example, regardless of which approach Jacobson discloses, a "nerve stimulator" allegedly would be capable of detecting contact with a nerve because the functionality of a "nerve stimulator" would not be affected by whatever approach is disclosed by Jacobson.

Patent Owner argues that one of ordinary skill in the art would have understood that "the clearest path to a disc space is posterolaterally [and not direct lateral, as that term is used in these proceedings]." PO Resp. 21. Patent Owner further contends that Jacobson discloses "using a long spinal needle" to anesthetize the patient and that, based on this disclosure and the allegation that a posterolateral (and not "direct lateral") approach is the "clearest path" that avoids the bowel, one of ordinary skill in the art would have understood that Jacobson discloses a posterolateral approach and not a "direct lateral" approach. PO. Resp. 21–22. As previously described, however, Jacobson discloses a "lateral" approach, which includes a so-called "direct lateral" approach and illustrates such an approach. Patent Owner does not show persuasively that one of ordinary skill in the art, given these explicit teachings, would have understood that the apparent "direct lateral" approach of Jacobson is actually a "posterolateral" approach based on

Jacobson's disclosure of one choice of method of administering an anesthetic.

In any event, as Patent Owner indicates, Jacobson discloses a "go-no-go" indicator that determines if the needle can be used. If the needle of Jacobson cannot be used, "the procedure cannot be used on this particular patient." *Id*. at 21 (citing Ex. 1004, 5:23–36). In other words, Jacobson discloses that if the needle cannot be safely used on a particular patient, the procedure is not performed. Even assuming Patent Owner's contention to be correct that using a so-called "direct lateral" approach carries a risk of bowel perforation, Jacobson explicitly addresses any such potential complications of the procedure. Hence, we are not persuaded that the potential use (or non-use) of a needle in Jacobson would suggest to one of ordinary skill in the art of a particular route of entry of the needle in a patient.

Patent Owner argues that Jacobson discloses a procedure that "can 'be performed in approximately 15 minutes,'" and that one of ordinary skill in the art would have understood that performing the procedure using a "direct lateral" approach would have taken "significantly longer than" 15 minutes. *Id*. at 23 (citing Ex. 2038 ¶ 86). Based on this assumption, Patent Owner contends that Jacobson discloses a posterolateral approach. Jacobson discloses that "[i]nstruments constructed in accordance with the invention allow the procedure to be performed in approximately 15 minutes under only local anesthesia." Ex. 1004, 2:54–57.

Patent Owner's declarant (Dr. Barton L. Sachs) testifies that "[p]erforming such a procedure in 15 minutes is far more consistent with an approach that is [posterolateral] than one that is direct lateral" and that "[i]n my opinion, a direct lateral discectomy would take significantly longer than

15 minutes." Ex. 2038 ¶ 87. However, Dr. Sachs testifies that he is of the opinion that a 15 minute procedure is "consistent with" a posterolateral procedure, but does not assert or provide sufficient evidence to suggest that one of ordinary skill in the art would have understood that such a procedure taking 15 minutes or less would not have used the so-called "direct lateral" approach. In addition, even assuming Patent Owner's implication that performance of spinal fusion using the so-called "direct lateral" approach could never be completed within 15 minutes, we note that Dr. Sachs testifies that the so-called "direct lateral" approach takes longer than 15 minutes because such an approach "requires care to deal with anatomical structures such as the peritoneum, the bowel, vascular structures, and the psoas muscle." Ex. 2038 ¶ 87. Jacobson discloses that the procedure takes "approximately 15 minutes under only local anesthesia," suggesting that Jacobson's time estimate of 15 minutes would not include the time for administering anesthesia (or advancing a needle to administer the anesthetic). Hence, one of ordinary skill in the art would have understood that the alleged "rate-limiting" step (according to Dr. Sachs) of dealing with the bowel, for example, would not be included in Jacobson's time estimate of 15 minutes. Dr. Sachs (and Patent Owner) does not demonstrate that one of ordinary skill in the art would have understood that the so-called "direct lateral" approach must take longer than 15 minutes, even after the "anatomical structures" that Dr. Sachs cites are already "dealt with."

Patent Owner argues that Jacobson discloses "placement of a patient in a lateral decubitus position [that] does not necessarily mean his approach is directly lateral." PO Resp. 23. Patent Owner does not demonstrate sufficiently, however, that one of ordinary skill in the art would have

understood that placement of a patient in a lateral decubitus position would mean necessarily the approach is something other than the so-called "direct lateral" approach, particularly in view of the previously discussed disclosure of Jacobson suggesting to one of ordinary skill in the art that the approach disclosed is the so-called "direct lateral" approach.

Jacobson discloses that the surgical procedure is a "fusion" surgical procedure. Ex. 1004, 6:13. Petitioner states that "a 'fusion' procedure . . . necessarily includes the insertion of an implant into the disc space." Pet. 19. Hence, Petitioner argues that Jacobson discloses or suggests an implant. Patent Owner argues that a fusion surgical procedure "can be with or ***without*** an implant" and that an "[i]nherent disclosure by a prior art reference 'is appropriate only when the reference discloses prior art that must ***necessarily*** include the unstated limitation.'" PO Resp. 25 (citing Ex. 2039, 26:23 – 27:1). Hence, Patent Owner argues that a fusion surgical procedure does not necessarily include the insertion of an implant.

Based on the record, we agree with Patent Owner that a "fusion" surgical procedure does not require the insertion of an implant in every instance. Therefore, we agree with Patent Owner that a "fusion" surgical procedure does not "necessarily" include the insertion of an implant. We disagree, however, with Patent Owner's implication of a requirement of showing a claim limitation is inherently present in a prior art reference to support a prima facie showing of obviousness of the disputed claims over a combination of references. For example, a "single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005). In the present case, the ground of

unpatentability in dispute is not "by anticipation." Hence, whether the "fusion" surgical procedure of Jacobson "necessarily" includes insertion of an implant has not been shown to be relevant to the present proceedings.

Brantigan – "implant being sized to occupy substantially the full transverse widths of the vertebral bodies"[4]

Claim 17 recites the length of an implant being sized to occupy substantially the full transverse widths of the vertebral bodies of the two adjacent vertebrae. Petitioner argues that Brantigan discloses or suggests this feature. *See, e.g.*, Pet. 28. Patent Owner argues that Brantigan discloses implants that are "***shaped*** to conform with the general outline perimeter of the vertebrae," but fails to disclose or suggest that "the implant is ***sized*** to trace the outline perimeter of the [vertebrae]." PO Resp. 34. As Petitioner points out, however, Brantigan discloses, for example, a "plug . . . generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column." Ex. 1006, 4:6–8. Hence, Brantigan discloses an implant that is both shaped and sized with regard to the disc space.

Patent Owner argues that Brantigan discloses an implant "that is designed to sit within the apophyseal ring" and "designed to sit in the central region of adjacent vertebral bodies where bone tends to be more cancellous and vascular." PO Resp. 36–37 (citing Ex. 1006, 2:15–16, Fig. 1; Ex. 2041, 1520:2–16; Ex. 2039, 50:1–10; Ex. 2038 ¶ 110). Hence, Patent Owner argues that Brantigan fails to disclose an implant that includes (or overlaps)

[4] Patent Owner argues that "[c]ollateral estoppel precludes Petitioner from relitigating its rejected interpretation of the disclosures of Brantigan." PO Resp. 39. After careful consideration, we are not persuaded by Patent Owner's arguments for at least the reasons previously stated. *See, e.g.*, Dec. on Inst. 13.

the apophyseal ring of a vertebral body or extends beyond a central region of a vertebral body. As previously described, claim 17 recites an implant being sized to occupy substantially the full transverse width of the vertebral body. Patent Owner does not show that claim 17 also recites an implant being sized to extend onto the apophyseal ring of the vertebral body or an implant being sized to extend beyond a central region of a vertebral body. Nor does Patent Owner point to an explicit disclosure in the Specification regarding the length of the implant with respect to the alleged "apophyseal ring." We, therefore, are not persuaded by Patent Owner's contention.

Patent Owner argues that Brantigan discloses an implant "conforming in shape and size with opposing ***hard end plates*** of vertebrae'" that does not "include the outer periphery (or apophyseal ring) of a vertebral body" or "***the entire vertebral body***." PO Resp. 34 (citing Ex. 2038 ¶ 29). As an initial matter, claim 17 recites an implant being sized to occupy substantially the full transverse width of the vertebral body. Hence, claim 17 requires that the implant occupy "a length that is less than the full transverse width of the vertebral bodies by an insubstantial amount." Dec. on Inst. 9. Patent Owner does not demonstrate that claim 17 requires that the implant includes "the entire vertebral body."

Also, as discussed above, Brantigan discloses that the implant is "sized to conform with the disc space between adjoining vertebrae." Ex. 1006, 4:6–7. We construe the term "disc space" recited in claim 17 broadly but reasonably and in light of the Specification to include a space between adjacent vertebral bodies. We agree with Petitioner that it would have been obvious to one of ordinary skill in the art that an implant that is "sized to conform with the disc space," as disclosed by Brantigan, would have

occupied at least a length that is less than the full transverse width of the vertebral bodies by an insubstantial amount (i.e., occupying "substantially" the full transverse width). Otherwise, an implant that does not occupy "substantially" the full transverse width would not have been sized to conform to the disc space, in contrast to Brantigan's disclosure that the implant is, in fact, sized to conform to the disc space.

Dr. Sachs testifies that the vertebral body contains a "vertebral endplate " that "is typically vascular," an "apophyseal ring" "anatomically distinct from the vertebral endplate" and "almost entirely avascular" located "[t]oward the vertebral periphery," and a "cortical rim" "distinct from the apophyseal ring" located "[a]t the very edge of the vertebral body." Ex. 2038 ¶ 29.

While Dr. Sachs provides testimony on the anatomy of the intervertebral space and disc, Dr. Sachs does not appear to provide testimony supporting Patent Owner's implied contention that one of ordinary skill in the art would have considered the term "occupying substantially the full transverse width of the vertebral body," as recited in claim 17, to mean "occupying no more than the width of the vertebral endplate" or "occupying (or not occupying) any portion of the apophyseal ring." Hence, even assuming that Dr. Sachs' characterization of the anatomy of the intervertebral disc space and vertebral bodies is correct, the testimony of Dr. Sachs provides insufficient evidence to refute the prima facie showing that it would have been obvious to one of ordinary skill in the art that an implant that is "sized to conform with the disc space," as disclosed by Brantigan, would occupy "substantially" the disc space (i.e., including a length that is less than the full transverse width of the vertebral bodies by an insubstantial

amount). In addition, even assuming claim 17 requires the length of the implant to overlap onto the "apophyseal ring" (claim 17 does not recite this requirement, however), the length of the implant of Brantigan would have included both the alleged "vertebral endplate" and the alleged "apophyseal ring" because both of these alleged structures overlie the space between adjacent vertebral bodies (i.e., the "disc space").

Patent Owner argues that Brantigan "expressly teaches an implant that is designed to sit within the apophyseal ring" as illustrated in Figure 10 of Brantigan, which, according to Patent Owner, "shows the implant 11 sitting well within the apophyseal ring." PO Resp. 36 (citing Ex. 1006 at Fig. 10). We note that Brantigan illustrates an implant within an intervertebral space in Figure 10; however, Patent Owner does not show persuasively that Brantigan "expressly teaches" that the implant illustrated in Figure 10 sits "within the apophyseal ring." For example, Brantigan does not appear to label any structure within Figure 10 as the "apophyseal ring." Nor does Patent Owner point to a disclosure in the textual portion of Brantigan indicating that the implant as illustrated in Figure 10 (or any other figure in Brantigan) sits "within the apophyseal ring." Indeed, as previously described, Brantigan appears to disclose the opposite (i.e., that the implant is "sized to conform with the disc space"). We, therefore, agree with Petitioner that one of ordinary skill in the art would not have understood that Brantigan discloses or suggests that the implant must not extend into the disc space encompassed by the apophyseal ring (not having been disclosed or suggested by Brantigan).

Patent Owner argues that "a figure in Brantigan . . . was admittedly drawn incorrectly." PO Resp. 36 (citing Ex. 2041, 1516:13–25, 1517:6–12;

Ex. 2039, 44:5–14). In particular, Patent Owner argues that Figure 11 of Brantigan allegedly contains discrepancies regarding the direction of insertion of the implant into the intervertebral space. *See, e.g.*, Ex. 2041, 1516:13–25. We are not persuaded by Patent Owner's argument at least because, even if Figure 11 discloses discrepancies regarding the direction of insertion of the implant, Patent Owner does not show persuasively that any such errors in Figure 11 sufficiently refute the prima facie case of obviousness that it would have been obvious to one of ordinary skill in the art to have provided an implant sized to occupy "substantially the full transverse widths of the vertebral bodies" given Brantigan's explicit disclosure that the implant is "sized to conform with the disc space."

Patent Owner argues that Brantigan discloses an implant that "can be rotated or reversed and still fit the vertebrae." PO Resp. 37 (citing Ex. 1006, 2:24–25; Ex. 2038 ¶ 113). Given that the implants of Brantigan are inserted "to support and fuse with adjacent vertebrae" (Ex. 1006, 1:65–66), we agree with Petitioner that one of ordinary skill in the art would have understood not to remove an implant once already inserted because doing so would not have permitted the implant to have provided the support desired or to have fused with adjacent vertebrae, as Brantigan discloses. Thus, we agree that one of ordinary skill in the art would have understood that Brantigan discloses that the implant of Brantigan may be selected to be inserted in any desired orientation (i.e., "rotated or reversed" prior to insertion so that the implant will "still fit the vertebrae").

In any event, regardless of which construction of "rotated or reversed and still fit the vertebrae" is used, as discussed previously, Brantigan discloses that the implant is "sized to conform with the disc space," which

one of ordinary skill in the art would have understood to mean sized to occupy substantially the full transverse widths of the vertebral bodies for reasons previously stated.

Patent Owner argues that Brantigan discloses "an anterior approach to the spine," as opposed to a lateral approach. PO Resp. 27. As previously discussed, Jacobson discloses or suggests this feature. We need not determine whether one of ordinary skill in the art would have understood Brantigan to also disclose this feature.

Leu – "interbody intraspinal implant"

Patent Owner argues that Leu discloses a "graft conglomerate" that, according to Patent Owner "is not a spinal fusion implant." PO Resp. 48 (citing Ex. 2038 ¶¶ 89, 97–99). Claim 17 recites an "interbody intraspinal implant." Patent Owner's declarant (Dr. Sachs) testifies that Leu discloses that the "graft conglomerate" contains "impacted bone" and "soft cancellous bone" that "is not a structural implant as claimed by the '997 [patent]." Ex. 2038 ¶ 97. Hence, Patent Owner appears to argue that one of ordinary skill in the art would have understood that an "interbody intraspinal implant," as recited in claim 17, must not contain "impacted bone" or "soft cancellous bone" such that the implant is not a "structural implant."

Patent Owner does not demonstrate that claim 17 recites that the "interbody intraspinal implant" must not contain "impacted bone" or "soft cancellous bone." Nor does Patent Owner indicate that the '997 patent specification discloses this explicit definition of the term. While Patent Owner's declarant (Dr. Sachs) testifies that "this graft conglomerate [of Leu] is not a structural implant as claimed by the '997 [patent]," Ex. 2038 ¶ 97,

Petitioner's declarant (Dr. McAfee) testifies that "nothing in Leu's suggestion for the 'porous apatite' graft . . . required an ordinary spinal surgeon . . . to limit his or her thoughts only to 'bits of porous apatites'" and that "spinal surgeons of ordinary skill understood that various non-bone elements were inserted into the disc space as part of conventional interbody fusion." Ex. 1029 ¶ 57. Hence, even if one of ordinary skill in the art would have understood that an "interbody interspinal implant," as recited in claim 17, must have provided structural support and that a "graft conglomerate" containing only "impacted bone" and "soft cancellous bone" would have provided insufficient structural support to be characterized as an "interbody intraspinal implant" (as Dr. Sachs testifies), we credit Dr. McAfee's testimony that one of ordinary skill in the art would have also understood that "non-bone elements were inserted into the disc space as part of conventional interbody fusion," to provide sufficient structural support to be classified as an "interbody interspinal implant."

In any event, Dr. McAfee also testifies that it would have been obvious to one of ordinary skill in the art to have "employ[ed] an implant structure *having a size/structure suggested by Brantigan* in the resulting surgical method of Jacobson in view of Leu." Ex. 1029 ¶ 57. Hence, Petitioner and Dr. McAfee argue that Brantigan also discloses an "interbody intraspinal implant," as recited in claim 17. Patent Owner does not appear to contest Petitioner's contention.

"Elongated portion"

Patent Owner argues that Jacobson fails to disclose or suggest an "elongated portion," as recited in claim 17 because, according to Patent

Owner, "[t]hese portions [as disclosed by Jacobson] are not 'positioned over' adjacent vertebrae." PO Resp. 50. Petitioner explains that Jacobson discloses "wires [that] are indeed positioned over the vertebrae." Pet. Reply 12, *see also* Pet. 26–27; Ex. 1029 ¶¶ 54–55. As Petitioner explains, Jacobson appears to disclose anchor wires (i.e., "elongated portions") that are positioned over adjacent vertebrae. Ex. 1030, Fig. 5. Patent Owner does not provide sufficient evidence of specific differences between the "elongated portion" being "positioned over" adjacent vertebrae, as recited in claim 17, and the "anchor wires" (that are "elongated portions") that are also "positioned over" adjacent vertebrae. We, therefore, are not persuaded by Patent Owner's argument.

Jacobson, Leu, Brantigan - combinability

Patent Owner argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Jacobson, Leu, and Brantigan. PO Resp. 50–53. Jacobson discloses advancing instruments laterally into the disc space to perform a "fusion" procedure. Ex. 1004, 5:1–4, 6:11–13. Leu discloses fusion of the lumbar spine by introducing an "interbody graft" into the disc space. Ex. 1005, p. 603. Brantigan, like Leu, discloses "prosthetic implant devices" that are "suitable for . . . lateral placement in any area of the spine." Ex. 1006, 2:56–58. We agree with Petitioner that the combination of the known element of performing a spinal fusion procedure by laterally advancing instruments into the disc space (Jacobson) with the known element of using an "interbody graft" in a spinal fusion procedure (Leu and Brantigan) would have resulted in no more than the predictable and expected result of performing a spinal fusion procedure

(Jacobson) that includes inserting an implant into a disc space (Leu or Brantigan). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007).

Patent Owner argues that one of ordinary skill in the art would not have combined the teachings of Jacobson with Leu because "the sequential dilators [of Leu] would *widen the perforation* [caused by a needle puncture to the patient's intestines] without any warning to the surgeon." PO Resp. 51. We are not persuaded by Patent Owner's argument at least because none of Jacobson or Leu supports the contention made.

Patent Owner also argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Brantigan with any of Jacobson or Leu because, according to Patent Owner, Brantigan "teaches away from sizing an implant to rest on the apophyseal ring or be sized to occupy substantially the full transverse width of adjacent vertebral bodies." PO Resp. 51–52, 55–56. This issue was discussed previously above.

Patent Owner also argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Brantigan with any of Jacobson or Leu because the "cannulae disclosed by Jacobson and Leu are too narrow to accommodate Brantigan's implant," that "a person of ordinary skill in the art would not be able to insert [Brantigan's] implant in Jacobson's [system]," and that "the shape of the Brantigan implant is not conducive to insertion through a cannula or similar surgical instrument [as disclosed by Jacobson or Leu]." PO Resp. 52–53. In other words, Patent Owner argues that the combination of Jacobson, Brantigan, and Leu would

not have been obvious to one of ordinary skill in the art because the prior art systems are not physically combinable (i.e., Brantigan's implant allegedly cannot be physically combined with the cannula of either Jacobson or Leu). "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference . . . . Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981); *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."). We are thus not persuaded by Patent Owner's argument.

Secondary considerations

We recognize that evidence of secondary considerations must always be considered en route to the determination of obviousness, but its existence alone does not control the conclusion of obviousness. *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). The weight given to evidence of secondary considerations is dependent upon whether there is a nexus between the merits of the claimed invention and the evidence offered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983).

Commercial Success

Patent Owner argues non-obviousness based on alleged commercial success of the claimed invention. PO Resp. 56–57. Patent Owner contends that Petitioner's product (i.e., the "XLIF procedure and CoRoent XL implants") and Patent Owner's product (i.e., the "DLIF procedure and

Clydesdale and Capstone L implants") have "enjoyed tremendous commercial success," based on "100,000 spinal levels" having been treated since 2003, sales of Petitioner's product of "$250M from May 2004 to June 2010," and sales of Patent Owner's product of over "$50M over approximately the same time period." PO Resp. 56–57 (citing Ex. 2038 ¶ 136; Ex. 2045, 47; Ex. 2046–2048).

Even assuming the sales figures quoted by Patent Owner for both Petitioner's product and Patent Owner's product are correct, and assuming that these sales figures represent "commercial success," Patent Owner has not demonstrated a sufficient nexus between the merits of the claimed invention and the evidence offered. Patent Owner contends that "in order to encourage surgeons to select its product, Petitioner touts the CoRoent XL implant as having the patent features of the '997 patent, such as a 'large foot print,' 'spans ring apophysis,' and 'maximizes fusion surface area.'" PO Resp. 57 (citing Ex. 2049, 21). We note that Patent Owner does not show that any of "large foot print," "spans ring apophysis," or "maximizes fusion surface area" is recited in the claims of the '997 patent. Not having identified any specific features in the claims of the '997 patent that form the basis for the commercial success of Petitioner's product, Patent Owner does not show persuasively a nexus between the claimed invention and the evidence proffered.

In addition, even assuming that these features are recited in the claims of the '997 patent, Patent Owner still does not demonstrate a sufficient nexus between these specific alleged features and the evidence relied upon to demonstrate commercial success (i.e., sales figures). Upon review of the marketing materials cited by Patent Owner, we observe that in addition to a

"large foot print," "spans ring apophysis," and "maximizes fusion surface area," the marketing materials also allege other benefits of the marketed product such as "minimal soft tissue/muscle damage," "reduced post-operative morbidity," "outpatient or 23 hr procedure," "adequate exposure," "safe and reproducible," and "meet or exceed traditional results." Ex. 2049, 17. Patent Owner provides insufficient evidence to show which of these alleged benefits of the marketed product (if any) would have resulted in (i.e., had a "nexus" to) the "commercial success" (i.e., sales revenue) alleged by Patent Owner.

Industry Praise

Patent Owner argues non-obviousness based on "industry praise" allegedly attributed to the claimed invention. PO Resp. 58–59. Industry praise must also be linked to the patented invention. *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1352 (Fed. Cir. 2010). Patent Owner cites to "Back.com," in which Dr. Richard Hynes states the benefits of the DLIF [Direct Lateral Interbody Fusion] procedure are that "you're approaching the disc from the side rather than from the front or back." Ex. 2050, p. 3. Petitioner has demonstrated that this feature (i.e., "direct lateral" approach), as discussed above, is disclosed by Jacobson. Hence, the feature that is allegedly praised was already present in the prior art. Under those circumstances, any evidence of secondary considerations stems from what was known in the prior art, so that there can be no nexus. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011) ("If [secondary considerations are] due to an element in the prior art, no nexus exists.").

Dr. Hynes alleges additional benefits of DLIF including "a very small, 1-2 cm incision," no "big incisions," no "cutting through muscles," "patients were in and out of the OR in less than an hour," and there was "major stabilization with no blood loss." Ex. 2050, p. 3. Patent Owner does not demonstrate sufficiently that any of these additional allegedly praiseworthy features are recited in the '997 patent claims. Hence, Patent Owner fails to demonstrate sufficiently a nexus between the alleged praise and the claimed invention.

Patent Owner also cites to Rose Mary Budge, "A New Solution," 2004–2009, available at http://www.spinaldoc.com/NuVasive_Spinal_Surgery.php. ("Budge," Ex. 2051). Budge discloses the procedure "involves side entry to the surgical [site] rather than from the back or the front." Ex. 2051 at 1. As previously described, this "praise," to the extent that this objective statement of the direction of entry to the surgical site can be considered "praise" at all, was known in the prior art (e.g., Jacobson), so that there can be no nexus. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011).

Budge further states other benefits of the procedure, including that the procedure is "less intimidating than the traditional methods," "can significantly lessen collateral damage," causes "less tissue trauma, less scarring, less blood loss and less post-operative discomfort." Ex. 2051 at 1. As previously described, Patent Owner does not show sufficiently a nexus between any of these additional allegedly praiseworthy features and the claimed invention because Patent Owner does not demonstrate that any of these features are recited in the claims of the '997 patent.

Patent Owner also cites to PR Newswire, "26 Technologies Receive 2009 Spine Technology Awards," 2009 ("PR Newswire," Ex. 2052) as demonstrating that "Petitioner's XLIF was selected as a 'Best New Technology for 2009' by Orthopedics This Week, an industry publication, and won an award in the "Minimally Invasive Care' category." PO Resp. 58. Even assuming that the "XLIF" won an award as Patent Owner asserts, Patent Owner does not show sufficiently that this award (or praise) had a nexus to a claim feature of the '997 patent (or which claim feature that might be).

Patent Owner further argues that Dr. Michelson testifies that Mr. Larry Boyd (presumably an officer at Sofamor Danek) had, for the first time, "seen a lateral retroperitoneal [approach]" at some point in time. PO Resp. 59 (citing Ex. 2041, 195:24 – 196:2). According to Patent Owner, officers at Sofamor Danek were "'very excited' about Dr. Michelson's technology and moved quickly to acquire it by signing a license agreement." PO Resp. 59 (citing Ex. 2041, 68:7–15). Patent Owner does not provide sufficient evidence explaining what features caused officers at Sofamor Danek to become "very excited" or why the officers allegedly "moved quickly" to sign a license agreement or how any alleged excitement or speed in the signing of license agreements pertains to specific features recited in claim 17. Hence, Patent Owner does not show a sufficient nexus between the claimed invention and the activities alleged to constitute "praise."

Copying

Patent Owner argues non-obviousness based on alleged copying of the claimed invention by competitors. PO Resp. 59–60. "[C]opying by a

competitor may be a relevant consideration in the secondary factor analysis." *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) (citing *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed.Cir.1984). "[A] nexus between the copying and the novel aspects of the claimed invention must exist for evidence of copying to be given significant weight in an obviousness analysis." *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012) (internal quotation omitted). Copying as objective evidence of nonobviousness requires evidence of effort to replicate a specific product. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Iron Grip*, 392 F.3d at 1325. Generally, evidence of alleged copying may be given little weight when the copy is not identical to the product embodying the claimed invention. *See Pentec, Inc. v. Graphic Controls, Corp.*, 776 F.2d 309, 317 (Fed. Cir. 1985).

Patent Owner asserts that Petitioner "worked on an early lateral access project called 'ELIF,' which stood for Extreme Lateral Interbody Fusion," trademarked the term "XLIF—for eXtreme Lateral Interbody Fusion" for the product, and eventually "evolved into a profitable company." PO Resp. 60 (citing Ex. 2041, 329:14–25, 434:2 – 435:14, 573:9 – 574:5, 979:19–24). Patent Owner also states that "prototypes created by Dr. Michelson included an implant with a 42 mm length, a distractor, outer sleeve, and other instruments." PO Resp. 60 (citing Ex. 2004). Patent Owner does not demonstrate sufficiently that the alleged copy (i.e., "ELIF" or "XLIF") is identical to the product embodying the claimed invention. Therefore, little weight is accorded to Patent Owner's allegations of copying. To the extent that Patent Owner argues that the "ELIF" or "XLIF" systems utilize implants

measuring 42 mm in length, a distractor, outer sleeve, and "other instruments," Patent Owner does not demonstrate that such a system embodies the claimed invention. For example, Patent Owner does not show that any of the claims of the '997 patent recite that the implant measures 42 mm in length and does not explain what the "other instruments" entail.

We have considered the evidence presented, but do not discern that it adequately establishes that the pertinent products are replications of a product that includes all the features of claim 17 of the '997 patent. In any event, even assuming that the noted "ELIF" or "XLIF" products do incorporate all the features of claim 17, it is not the case that "every competing product that arguably falls within the scope of a patent is evidence of copying." *IronGrip*, 392 F.3d at 1325. Rather, as noted above, copying requires the "replication" of a specific product. *Id*.

Patent Owner does not provide additional arguments or evidence with respect to claims 18–22. We are persuaded, by a preponderance of the evidence, that claims 17–23 are unpatentable over the combination of Jacobson, Leu, and Brantigan.

B. Grounds Based at least in part on Jacobson, Leu, and Michelson '247 (Claims 9–16 and 24–30)

Claim 9 recites the length of an implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae. Claim 24 recites the length of an implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae. Michelson '247 discloses "an artificial fusion implant to be placed into the intervertebral space left after the removal of a damaged spinal disc" in which a drill is used that is "such a length that it can not

penetrate more than **28** millimeters beyond the end of the drill sleeve" so that "the implant . . . is able to be inserted only 28 millimeters." Ex. 1008, 1:5–7; 9:40–42; 10:31–32. Michelson '247 also discloses that "the implant . . . is only 26 millimeters in length . . . [which] guarantees that the implant . . . will be recessed into the vertebral bodies more than 2 millimeters and can not protrude into the spinal canal." Ex. 1008, 10:32–36. While Michelson '247 discloses an implant that measures 26 millimeters in length and is inserted into a drilled opening that is 28 millimeters in length, Petitioner does not demonstrate sufficiently that Michelson '247 also discloses that the implant must occupy either substantially the full transverse width of the vertebral body (as recited in claim 9) or the full transverse width of the vertebral body (as recited in claim 24). For example, Michelson '247 merely discloses a specific length of 26 millimeters for the length of the implant (26 millimeters) and a specific length of a drilled opening (28 millimeters), but does not disclose the length of the implant (or opening) in relation to the size of the vertebral body.

Michelson '247 further discloses that the drill may be "varied and made smaller for enhanced safety," but does not appear to disclose elongating the drill to a length greater than 28 millimeters. Ex. 1008, 9:42–43. That further demonstrates that Michelson '247 fails to disclose or suggest sizing the implant to obtain the maximum sized implant with respect to the size of the vertebral body. Instead, Michelson '247 appears to suggest using only smaller sized implants "for enhanced safety."

Petitioner argues that Michelson '247 discloses "the length of the implant extend[s] longitudinally across nearly the full disc space along the direction of insertion." Pet. 10. Regarding claim 24, Petitioner does not

assert or demonstrate sufficiently that Michelson '247 discloses or suggests an implant sized to occupy the *full* transverse width of the vertebral bodies. In any event, as Patent Owner points out, "there is ***nothing in the written disclosure*** of Michelson '247 that teaches a surgeon to size an implant to span as much of the length as possible from an anterior to posterior direction." PO Resp. 41 (citing Ex. 2039, 44:16–19; 45:6–16). Petitioner does not point out where specifically Michelson '247 discloses or suggests this feature.

Petitioner argues that Patent Owner does not argue Michelson '247 discloses an implant that would not rest on the apophyseal ring or that the implant is designed to rest only on a spongy center part of the vertebrae and that "the '997 patent's drill has the very same feature [as the drill disclosed by Michelson '247]." Pet. Reply 11. Even assuming Petitioner's allegations to be correct, Petitioner still does not demonstrate persuasively that Michelson '247 discloses or suggests an "implant being sized to occupy the full" (or "substantially full") dimension of the vertebral body, as recited in claim 9 or claim 24.

Claims 10–16 depend from claim 9 and claims 25–30 depend from claim 24. We are not persuaded that claims 9–16 and 24–30 would have been obvious over the combination of Jacobson, Leu, and Michelson '247.

C. Motion to Exclude

In its Motion to Exclude, Patent Owner seeks to exclude the following documents:

1. Declaration of Dr. Paul McAfee ("McAfee Declaration," Ex. 1001, 54–85);
2. Affidavit of Henry Vernon Crock (Ex. 1014–1021);

3. Second Declaration of Dr. Paul McAfee (Ex. 1029 ¶¶ 4, 7, 9, 10, 37–39, 43–45, 48, and 49);
4. Declaration of Dr. Robert E. Jacobson ("Jacobson Declaration," Ex. 1030 ¶¶ 4–6, 8, and 10);
5. Declaration of Patrick Miles ("Miles Declaration," Ex. 1032 ¶ 9);
6. William A Friedman, *Percutaneous Discectomy: An Alternative to Chemonucleolysis?*, NEUROSURGERY, Vol. 13, No. 5 (1983) ("Friedman Article," Ex. 1036);
7. Steven L. Kanter and William A. Friedman *Percutaneous Discectomy: An Anatomical Study*, NEUROSURGERY, Vol. 16, No. 2 (1985) ("Kanter Article," Ex. 1037);
8. Medtronic Corporate Structure (Ex. 1046);
9. Gregory M. Malham, et al., *Clinical Outcome and Fusion Rates after the First 30 Extreme Lateral Interbody Fusions*, THE SCIENTIFIC WORLD JOURNAL (2012) ("Malham Article," Ex. 1049);
10. Armen R. Deukmedjian, *Bowel and Vascular Injury Following 13,000 Lateral Interbody Fusions*, SMISS 2013 ANNUAL CONFERENCE ("Deukmedjian Article," Ex. 1050); and
11. Paul C. McAfee, et al., *Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine*, SPINE, Vol. 23, No. 13 (1998) ("McAfee Article," Ex. 1067).

For the reasons discussed below, the motion is dismissed.

Second Declaration of Dr. Paul McAfee – Ex. 1029 ¶ 38

Patent Owner alleges that the Second Declaration of Dr. Paul McAfee (Ex. 1029 ¶ 38) should be excluded because, according to Patent Owner,

"Dr. McAfee wrongly relies on Dr. Jacobson's declaration (Exhibit 1030) about the alleged surgeries he performed prior to 1995," that "Dr. McAfee wrongly relies on the Crock Affidavit (Exhibit 1014) in paragraphs 7 and 9 of his second declaration about the surgeries Dr. Crock allegedly performed prior to 1995," which, according to Patent Owner, "are not relevant to whether the challenged claims are unpatentable in light of the prior art patents and printed publications in the instituted claims." Paper 53 at 6.

The Second Declaration of Dr. Paul McAfee, however, is not relied upon for any alleged surgeries performed by Dr. Crock or Dr. Jacobson prior to 1995 (or at any other time). Rather, the Second Declaration of Dr. Paul McAfee is relied upon to support what one of ordinary skill in the art would have understood based on Figure 6 of the '997 patent at the time of the invention (see above). Ex. 1029 ¶ 38. Thus, we are not persuaded that the Second Declaration of Dr. Paul McAfee (at ¶ 38) should be excluded.

Jacobson Declaration – Ex. 1030 ¶ 5

Patent Owner moves to exclude the Jacobson Declaration (Ex. 1030 ¶ 5) based on various bases. Patent Owner alleges that the Jacobson Declaration (Ex. 1030 ¶ 5) "include[s] what Dr. Jacobson was allegedly ***doing*** prior [to] 1995, not what the Jacobson '374 reference discloses to a person of ordinary skill in the art." Paper 53, 9–10.

The Jacobson Declaration (Ex. 1030 ¶ 5) is relied upon to ascertain what one of ordinary skill in the art would have understood by the terms "lateral" and "direct lateral" at the time of the invention (see above) and is not relied upon for any procedures Dr. Jacobson may or may not have been

alleged to have performed prior to 1995. Thus, we are not persuaded that the Jacobson Declaration (at ¶ 5) should be excluded.

Other Evidence

As previously described, Patent Owner moves to exclude other evidence, none of which was relied upon by the Board. Therefore, Patent Owner's motion to exclude is moot with respect to the other evidence.

ORDER

Petitioner has demonstrated, by a preponderance of the evidence, that claims 17–23 are unpatentable over Jacobson, Leu, and Brantigan under 35 U.S.C. § 103(a). Petitioner has not demonstrated, by a preponderance of the evidence, that claims 9–16 are unpatentable over Jacobson, Leu, McAfee, and Michelson '247 under 35 U.S.C. § 103(a) or that claims 24–30 are unpatentable over Jacobson, Leu, and Michelson '247 under 35 U.S.C. § 103(a).

In consideration of the foregoing, it is hereby:

ORDERED that claims 17–23 of the '997 patent have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *dismissed*.

This is a final decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2013-00206
Patent 8,251,997 B2

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Paper 62
Date: July 10, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

WARSAW ORTHOPEDIC, INC.,
Patent Owner.

Case IPR2013-00208
Patent 8,251,997 B2

Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges.*

SIU, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

NuVasive, Inc. ("Petitioner") filed a petition (Paper 5) ("Pet.") seeking *inter partes* review of claims 1–8 of U.S. Patent No. 8,251,997 B2 (Ex. 1002, "the '997 patent") pursuant to 35 U.S.C. §§ 311-319.[1] On

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[1] We cite to Petitioner's Corrected Petition for *Inter Partes* Review of United States Patent No. 8,251,997 B2, filed April 3, 2013. Paper 5.

September 23, 2013, the Board instituted an *inter partes* review of all claims (Paper 16) ("Dec. on Inst.").

Subsequent to institution, Warsaw Orthopedic, Inc. ("Patent Owner") filed a Patent Owner Response (Paper 29) ("PO Resp."), and Petitioner filed a Reply (Paper 40) ("Pet. Reply"). Patent Owner also filed a Motion to Exclude Evidence. Paper 50. Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 56) ("Opp."), and Patent Owner filed a Reply (Paper 57) ("PO Reply").. An Oral Hearing was conducted on June 5, 2014, pursuant to a request for oral hearing filed by Petitioner (Paper 49) and Patent Owner (Paper 51).

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–8 of the '997 patent are unpatentable.

A. The '997 Patent (Ex. 1002)[2]

The '997 patent describes methods and instrumentation for performing surgery on the spine along its lateral aspect. Ex. 1002, 3:34–36; Figs. 1 and 2. Guide pin 30 is inserted from the lateral approach to the spine and functions as a guide post for distractor 100 that is placed over the guide pin and inserted into the disc space to distract the vertebrae. Ex. 1002, 8:52–53; 9:12–14; 10:10–12; Figs. 2–5. Extended outer sleeve 140 is placed over the distractor and inserted into the disc space. Ex. 1002, 10:22–25, Fig. 12. A spinal implant I is introduced through the extended outer sleeve and

[2] We refer to Ex. 1002 submitted by Petitioner and dated March 22, 2013.

installed across the disc space. Ex. 1002, 15:64–65; 16:24–26; Figs. 19, 22, 23, 30, and 30A.

B. Illustrative Claim

Claim 1 is illustrative of the claimed subject matter of the '997 patent, and is reproduced as follows:

> 1. A method comprising:
>
> making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;
>
> advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;
>
> advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;
>
> advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

positioning said third surgical instrument such that said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies of the two adjacent vertebrae; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, a non-bone interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

C. Cited Prior Art

The pending grounds of unpatentabililty in this *inter partes* review are based on the following prior art:

Jacobson	US 4,545,374	Oct. 8, 1985	(Ex. 1004)
Brantigan	US 5,192,327	Mar. 9, 1993	(Ex. 1006)
Frey	US 4,917,704	Apr. 17, 1990	(Ex. 1007)
Michelson ’247	US 5,015,247	May 14, 1991	(Ex. 1008)
Alcareu	EP 0567424	Oct. 27, 1993	(Ex. 1009)

Hansjörg F. Leu and Adam Schreiber; *Percutaneous Fusion of the Lumbar Spine: A Promising Technique*, 6(3) SPINE: STATE OF THE ART REVIEWS 593 (Sept. 1992) (Ex. 1005, “Leu”).

D. Pending Grounds of Unpatentability

This *inter partes* review involves the following asserted grounds of unpatentability:

Reference(s)	**Basis**	**Claims challenged**
Jacobson, Leu, and Michelson ’247	§103	1 and 8
Jacobson, Leu, and Brantigan	§103	1 and 8
Jacobson, Leu, Michelson ’247, and Alacreu	§103	2–7
Jacobson, Leu, Brantigan, and Frey	§103	2–7

E. Claim Interpretation

The parties appear to agree with the interpretation of various claim terms of the ’997 patent as described in the Decision on Institution with additions or modifications as set forth below. We incorporate our previous analysis for the non-disputed claim terms.

1. “a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes” (claim 1)

Patent Owner argues that an “axis lying in a coronal plane” should be construed as an axis that is lying in “a plane at right angles to a sagittal plane.” PO Resp. 10–11. Petitioner does not contest Patent Owner’s assertion that one of ordinary skill in the art would understand that a “coronal plane” would be oriented “at right angles to a sagittal plane.” Pet. Reply 1. Thus, no further construction of this term is necessary.

2. “non-bone interbody intraspinal implant” (claim 1)

Patent Owner argues that the term "non-bone interbody intraspinal implant" should be construed such that "the composition of the implant does not include any bone" because "the prefix 'non' is commonly understood to exclude the thing specified after the word." PO Resp. 12–13, citing Ex. 2038 ¶ 63. We agree that one of ordinary skill in the art would have understood that the prefix "non" indicates that the implant contains material that is not bone. Patent Owner does not show persuasively, however, that, under a broad but reasonable construction, one of ordinary skill in the art would have understood that it cannot contain any component derived from bone.

Hence, we broadly, but reasonably, construe a "non-bone interbody instraspinal implant" as an implant that contains at least one component that does not contain bone.

II. ANALYSIS

A. Grounds Based at Least in Part on Jacobson, Leu, and Brantigan (Claims 1–8)

Claim 1 recites a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae. Patent Owner contends that a path having an axis lying in a coronal plane, as recited in claim 1, must be a path that is "a direct or 'true' lateral path [to the spine]." PO Resp. 11. Petitioner concurs. Pet. Reply 1.

Jacobson – "lateral"

Jacobson discloses a procedure in which "a cannula is passed laterally through the body," a needle that "is inserted laterally through the patient's side" that "may act as a guide member . . . for instruments that create the

percutaneous body channel," a speculum that "is laterally inserted through body tissue" and is "used to create the lateral cavity through body tissue into which the cannula will be inserted." Ex. 1004, 5:1–2, 5:27–28, 5:49–51, 5:40–42, 8:53–55. Jacobson also provides drawings of the approach to the intervertebral space. The drawings depict a lateral approach to the intervertebral space, consistent with the textual description. Ex. 1004, Figs. 1–6.

Patent Owner argues that while Jacobson discloses accessing a disc space from a "lateral" aspect, the term "lateral" "has any number of meanings, including anterolateral, posterolateral, direct lateral, and lateral to the midline of the vertebral bodies" and that, despite Jacobson's disclosure of a "lateral" approach, Jacobson actually "discloses a posterolateral – not a direct lateral – approach to the spine." PO Resp. 19 (citing Ex. 2039, 37:25 – 39:1).

Petitioner provides testimony of Dr. Robert E. Jacobson to demonstrate what one of ordinary skill in the art would have understood the term "lateral" to mean in the context of performing a spinal fusion procedure. Ex. 1030 ¶ 5. Dr. Jacobson testifies that one of ordinary skill in the art would not have used (or understood) the term "direct lateral" but, instead, would have used the term "lateral" as Patent Owner uses the term in the present proceedings.[3] We credit Dr. Jacobson's testimony that one of ordinary skill in the art would have understood the term "lateral" to mean

[3] Dr. Jacobson testifies that "the phrase 'direct lateral' was not a phrase that I used in the technical parlance of my profession . . . at that time I had never heard the phrase 'direct lateral' to describe a 90 degree lateral approach to the spine. Instead, . . . I (and others) simply used the term 'lateral' when referring to a 90 degree lateral approach to the spine." Ex. 1030 ¶5.

what it says (i.e., to mean "lateral"), at least because it would have been reasonable for one of ordinary skill in the art to have construed a term (i.e., "lateral") with a plain and common definition. Patent Owner's observation that a construction of the term "lateral" that was in use at the time of the invention included a "direct lateral" approach (as understood in this proceeding) further supports Dr. Jacobson's testimony that one of ordinary skill in the art would have understood the term "lateral" to mean "direct lateral," as that term is presently construed in the instant proceedings. Also, we note that claim 1 does not recite the term "direct lateral," and Patent Owner does not assert that the '997 patent specification discloses the term "direct lateral." The absence of the term "direct lateral" in the '997 patent further supports that one of ordinary skill in the art at the time of the invention would not have used (or understood) the term "direct lateral."

In addition to Jacobson's explicit disclosure of, for example, "laterally inserting a cannula," Jacobson discloses figures that illustrate what Patent Owner now refers to as a "direct lateral" approach (i.e., lateral insertion along a path having an axis lying in a coronal plane). Ex. 1004, 2:26–27, Figs. 3–8. We note that in each of the figures of Jacobson, the outer side periphery of the instrument(s) inserted "laterally" into the intervertebral space, as illustrated, are depicted by parallel lines that are oriented at 90 degrees from a horizontal surface. Based on the depiction of the outer side contours of the instrument(s) as being oriented 90 degrees from a horizontal surface, one of ordinary skill in the art would have understood that the instrument(s) are perpendicular to an underlying horizontal surface in the superior-inferior perspective (with respect to the orientation of the patient). More importantly, as the outer side contours of the instruments are parallel

in these perspectives, one of ordinary skill in the art would have understood the instruments, as illustrated by Jacobson, to be perpendicular to an underlying horizontal surface in the medial-lateral perspective (with respect to the orientation of the patient – i.e., that the orientation of the instrument(s) is "direct lateral," as Patent Owner uses that phrase, and not "posterolateral" or "anterolateral"). That is true because, assuming the instrument(s) illustrated in Jacobson are cylindrical, if the instrument(s) were angled away from the viewer, the outer side contours of the instrument(s) at the point of insertion into the intervertebral space would appear farther away from each other as compared to the outer side contours of the instrument(s) at the point farthest from the point of insertion into the intervertebral space (i.e., the proximal end of the instrument(s), which would be located farther away from the viewer). Likewise, if the instrument(s) were angled toward the viewer, the outer side contours of the instrument(s) at the point of insertion into the intervertebral space would appear closer to each other as compared to the outer side contours of the instrument(s) at the point farthest from the point of insertion into the intervertebral space (i.e., the proximal end of the instrument(s), which is located closer to the viewer).

Moreover, as Petitioner's declarant (Dr. Paul McAfee) points out, an anterior cross sectional view of the instrument(s) in-situ (i.e., Ex. 1004, Fig. 6) shows an even and symmetrical view of the instruments throughout the length of the instrument(s). *See, e.g.*, Ex. 1029 ¶ 38. Dr. McAfee's testimony further supports that Jacobson discloses that the instruments are inserted along a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae, as recited

in claim 1 (i.e., the "direct lateral" approach as presently understood in the instant proceedings).

Patent Owner argues that the figures as disclosed by Jacobson "appear to show a direct lateral path," but "do not clearly show the surgical approach" because the figures "are merely two-dimensional depictions [that depict the same orientation]" and that "these figures [of Jacobson] could just as likely disclose a posterolateral or anterolateral approach to the spine." PO Resp. 23–24 (citing Ex. 2038 ¶ 81). Patent Owner does not explain adequately, however, how the anterior view of instrument(s) illustrated in Jacobson with parallel outer side contours as described above or the anterior cross sectional view of the instrument(s) throughout the length of the instrument(s) as also described above (i.e., instrument(s) that are normal to an underlying horizontal surface), "could just as likely" illustrate instrument(s) that are angled with respect to an underlying horizontal surface. While Patent Owner also argues that "surgeons are trained to orient an instrument in a patient's body by taking images of the instrument from multiple angles," Patent Owner does not demonstrate persuasively that, even if surgeons are trained to take images at multiple angles, that Jacobson illustrates that the instrument(s) are angled (i.e., a posterolateral or anterolateral approach). PO Resp. 24 (citing Ex. 2038, ¶ 81).

Patent Owner argues that Jacobson "discloses a method of performing percutaneous discectomy that implicates anatomical structures such as the spinal nerves and nerve root – structures that are encountered during a posterolateral (not direct lateral) approach to the spine" and a "stimulator [that] will cause motion in one of the patient's legs if it makes nerve contact [and that motor nerves are implicated only in a posterolateral approach.]"

PO Resp. 19–20 (citing Ex. 2038 ¶¶ 76–77; Ex. 1004, 6:38–40). As Patent Owner indicates, Jacobson discloses "[t]o prevent nerve damage, a nerve stimulator . . . may be attached or passed down into the cannula or trocar to indicate if either instrument is hitting one of the spinal nerves or exiting nerve branches." Ex. 1004, 6:32–38. It is not disputed that Jacobson discloses a "lateral approach" that includes a "direct lateral" approach, as construed in the instant proceedings (see discussion above). Also, as described above, Jacobson discloses illustrations of a spinal fusion procedure in which instruments are inserted into an intervertebral space (i.e., a "direct lateral" approach as presently understood) while oriented normal to an underlying horizontal surface (i.e., having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae). Patent Owner does not demonstrate sufficiently how Jacobson's further disclosure of the possible use of a "nerve stimulator" that indicates if an attached instrument contacts a nerve means that Jacobson does not disclose or suggest a ("direct") lateral approach. For example, regardless of which approach Jacobson discloses, a "nerve stimulator" allegedly would be capable of detecting contact with a nerve because the functionality of a "nerve stimulator" would not be affected by whatever approach is disclosed by Jacobson.

Patent Owner argues that one of ordinary skill in the art would have understood that "the clearest path to a disc space is posterolaterally [and not direct lateral, as that term is used in these proceedings]." PO Resp. 20. Patent Owner further contends that Jacobson discloses using "a spinal needle" to anesthetize the patient and that, based on this disclosure and the allegation that a posterolateral (and not "direct lateral") approach is the

"clearest path" that avoids the bowel, one of ordinary skill in the art would have understood that Jacobson discloses a posterolateral approach and not a "direct lateral" approach. PO. Resp. 21–22. As previously described, however, Jacobson discloses a "lateral" approach, which includes a so-called "direct lateral" approach and illustrates such an approach. Patent Owner does not show persuasively that one of ordinary skill in the art, given these explicit teachings, would have understood that the apparent "direct lateral" approach of Jacobson is actually a "posterolateral" approach based on Jacobson's disclosure of one choice of method of administering an anesthetic.

In any event, as Patent Owner indicates, Jacobson discloses a "go-no-go" indicator that determines if the needle can be used. If the needle of Jacobson cannot be used, "the procedure cannot be used on this particular patient." *Id.* at 21 (citing Ex. 1004, 5:23–36). In other words, Jacobson discloses that if the needle cannot be safely used on a particular patient, the procedure is not performed. Even assuming Patent Owner's contention to be correct that using a so-called "direct lateral" approach carries a risk of bowel perforation, Jacobson explicitly addresses any such potential complications of the procedure. Hence, we are not persuaded that the potential use (or non-use) of a needle in Jacobson would suggest to one of ordinary skill in the art of a particular route of entry of the needle in a patient.

Patent Owner argues that Jacobson discloses a procedure that "can 'be performed in approximately 15 minutes," and that one of ordinary skill in the art would have understood that performing the procedure using a "direct lateral" approach would have taken "significantly longer than" 15 minutes. *Id.* at 22 (citing Ex. 2038 ¶ 86). Based on this assumption, Patent Owner

contends that Jacobson discloses a posterolateral approach. Jacobson discloses that "[i]nstruments constructed in accordance with the invention allow the procedure to be performed in approximately 15 minutes under only local anesthesia." Ex. 1004, 2:54–57.

Patent Owner's declarant (Dr. Barton L. Sachs) testifies that "[p]erforming such a procedure in 15 minutes is far more consistent with an approach that is [posterolateral] than one that is direct lateral" and that "[i]n my opinion, a direct lateral discectomy would take significantly longer than 15 minutes." Ex. 2038 ¶ 87. However, Dr. Sachs testifies that he is of the opinion that a 15 minute procedure is "consistent with" a posterolateral procedure, but does not assert or provide sufficient evidence to suggest that one of ordinary skill in the art would have understood that such a procedure taking 15 minutes or less would not have used the so-called "direct lateral" approach. In addition, even assuming Patent Owner's implication that performance of spinal fusion using the so-called "direct lateral" approach could never be completed within 15 minutes, we note that Dr. Sachs testifies that the so-called "direct lateral" approach takes longer than 15 minutes because such an approach "requires care to deal with anatomical structures such as the peritoneum, the bowel, vascular structures, and the psoas muscle." Ex. 2038 ¶ 87. Jacobson discloses that the procedure takes "approximately 15 minutes under only local anesthesia," suggesting that Jacobson's time estimate of 15 minutes would not include the time for administering anesthesia (or advancing a needle to administer the anesthetic). Hence, one of ordinary skill in the art would have understood that the alleged "rate-limiting" step (according to Dr. Sachs) of dealing with the bowel, for example, would not be included in Jacobson's time estimate

of 15 minutes. Dr. Sachs (and Patent Owner) does not demonstrate that one of ordinary skill in the art would have understood that the so-called "direct lateral" approach must take longer than 15 minutes, even after the "anatomical structures" that Dr. Sachs cites are already "dealt with."

Patent Owner argues that Jacobson discloses "placement of a patient in a lateral decubitus position [that] does not necessarily mean his approach is directly lateral." PO Resp. 23. Patent Owner does not demonstrate sufficiently, however, that one of ordinary skill in the art would have understood that placement of a patient in a lateral decubitus position would mean necessarily the approach is something other than the so-called "direct lateral" approach, particularly in view of the previously discussed disclosure of Jacobson suggesting to one of ordinary skill in the art that the approach disclosed is the so-called "direct lateral" approach.

Jacobson discloses that the surgical procedure is a "fusion" surgical procedure. Ex. 1004, 6:13. Petitioner states that "a 'fusion' procedure . . . necessarily includes the insertion of an implant into the disc space." Pet. 18. Hence, Petitioner argues that Jacobson discloses or suggests an implant. Patent Owner argues that a fusion surgical procedure "can be with or ***without*** an implant" and that an "[i]nherent disclosure by a prior art reference 'is appropriate only when the reference discloses prior art that must ***necessarily*** include the unstated limitation.'" PO Resp. 25 (citing Ex. 2039, 26:23 – 27:1). Hence, Patent Owner argues that a fusion surgical procedure does not necessarily include the insertion of an implant.

Based on the record, we agree with Patent Owner that a "fusion" surgical procedure does not require the insertion of an implant in every instance. Therefore, we agree with Patent Owner that a "fusion" surgical

procedure does not "necessarily" include the insertion of an implant. We disagree, however, with Patent Owner's implication of a requirement of showing a claim limitation is inherently present in a prior art reference to support a prima facie showing of obviousness of the disputed claims over a combination of references. For example, a "single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005). In the present case, the ground of unpatentability in dispute is not "by anticipation." Hence, whether the "fusion" surgical procedure of Jacobson "necessarily" includes insertion of an implant has not been shown to be relevant to the present proceedings.

Brantigan – "implant being sized to occupy substantially the full transverse widths of the vertebral bodies"[4]

Claim 1 recites the length of an implant being sized to occupy substantially the full transverse widths of the vertebral bodies of the two adjacent vertebrae. Petitioner argues that Brantigan discloses or suggests this feature. *See, e.g.*, Pet. 28. Patent Owner argues that Brantigan discloses implants that are "***shaped*** to conform with the general outline perimeter of the vertebrae," but fails to disclose or suggest that "the implant is ***sized*** to trace the outline perimeter of the [vertebrae]." PO Resp. 34. As Petitioner points out, however, Brantigan discloses, for example, a "plug . . . generally shaped and sized to conform with the disc space between adjoining vertebrae

[4] Patent Owner argues that "[t]he doctrine of collateral estoppel precludes Petitioner from relitigating its rejected interpretation of the disclosures of Brantigan." PO Resp. 39. After careful consideration, we are not persuaded by Patent Owner's arguments for at least the reasons previously stated. *See, e.g.*, Dec. on Inst. 12.

in a vertebral column." Ex. 1006, 4:6–8. Hence, Brantigan discloses an implant that is both shaped and sized with regard to the disc space.

Patent Owner argues that Brantigan discloses an implant "that is designed to sit within the apophyseal ring" and "designed to sit in the central region of adjacent vertebral bodies where bone tends to be more cancellous and vascular." PO Resp. 36, 38 (citing Ex. 1006, 2:15–16 and Fig. 1; Ex. 2041, 1520:2–16; Ex. 2039, 50:1–10; Ex. 2038 ¶ 110). Hence, Patent Owner argues that Brantigan fails to disclose an implant that includes (or overlaps) the apophyseal ring of a vertebral body or extends beyond a central region of a vertebral body. As previously described, claim 1 recites an implant being sized to occupy substantially the full transverse width of the vertebral body. Patent Owner does not show that claim 1 also recites an implant being sized to extend onto the apophyseal ring of the vertebral body or an implant being sized to extend beyond a central region of a vertebral body. Nor does Patent Owner point to an explicit disclosure in the Specification regarding the length of the implant with respect to the alleged "apophyseal ring." We, therefore, are not persuaded by Patent Owner's contention.

Patent Owner argues that Brantigan discloses an implant "conforming in shape and size with opposing ***hard end plates*** of vertebrae'" that does not "include the outer periphery (or apophyseal ring) of a vertebral body" or "***the entire vertebral body***." PO Resp. 34–35 (citing Ex. 2038 ¶ 29). As an initial matter, claim 1 recites an implant being sized to occupy substantially the full transverse width of the vertebral body. Hence, claim 1 requires that the implant occupy "a length that is less than the full transverse width of the vertebral bodies by an insubstantial amount." Dec. on Inst. 9. Patent Owner

does not demonstrate that claim 1 requires that the implant includes "the entire vertebral body."

Also, as discussed above, Brantigan discloses that the implant is "sized to conform with the disc space between adjoining vertebrae." Ex. 1006, 4:6–7. We construe the term "disc space" of claim 1 broadly but reasonably and in light of the Specification to include a space between adjacent vertebral bodies. We agree with Petitioner that it would have been obvious to one of ordinary skill in the art that an implant that is "sized to conform with the disc space," as disclosed by Brantigan, would have occupied at least a length that is less than the full transverse width of the vertebral bodies by an insubstantial amount (i.e., occupying "substantially" the full transverse width). Otherwise, an implant that does not occupy "substantially" the full transverse width would not have been sized to conform to the disc space, in contrast to Brantigan's disclosure that the implant is, in fact, sized to conform to the disc space.

Dr. Sachs testifies that the vertebral body contains a "vertebral endplate " that "is typically vascular," an "apophyseal ring" "anatomically distinct from the vertebral endplate" and "almost entirely avascular" located "[t]oward the vertebral periphery," and a "cortical rim" "distinct from the apophyseal ring" located "[a]t the very edge of the vertebral body." Ex. 2038 ¶ 29.

While Dr. Sachs provides testimony on the anatomy of the intervertebral space and disc, Dr. Sachs does not appear to provide testimony supporting Patent Owner's implied contention that one of ordinary skill in the art would have considered the term "occupying substantially the full transverse width of the vertebral body," as recited in claim 1, to mean

"occupying no more than the width of the vertebral endplate" or "occupying (or not occupying) any portion of the apophyseal ring." Hence, even assuming that Dr. Sachs' characterization of the anatomy of the intervertebral disc space and vertebral bodies is correct, the testimony of Dr. Sachs provides insufficient evidence to refute the prima facie showing that it would have been obvious to one of ordinary skill in the art that an implant that is "sized to conform with the disc space," as disclosed by Brantigan, would occupy "substantially" the disc space (i.e., including a length that is less than the full transverse width of the vertebral bodies by an insubstantial amount). In addition, even assuming claim 1 requires the length of the implant to overlap onto the "apophyseal ring" (claim 1 does not recite this requirement, however), the length of the implant of Brantigan would have included both the alleged "vertebral endplate" and the alleged "apophyseal ring" because both of these alleged structures overlie the space between adjacent vertebral bodies (i.e., the "disc space").

Patent Owner argues that Brantigan "expressly teaches an implant that is designed to sit within the apophyseal ring" as illustrated in Figure 10 of Brantigan, which, according to Patent Owner, "shows the implant 11 sitting well within the apophyseal ring." PO Resp. 36 (citing Ex. 1006 at Fig. 10). We note that Brantigan illustrates an implant within an intervertebral space in Figure 10, however, Patent Owner does not show persuasively that Brantigan "expressly teaches" that the implant illustrated in Figure 10 sits "within the apophyseal ring." For example, Brantigan does not appear to label any structure within Figure 10 as the "apophyseal ring." Nor does Patent Owner point to a disclosure in the textual portion of Brantigan indicating that the implant as illustrated in Figure 10 (or any other figure in

Brantigan) sits "within the apophyseal ring." Indeed, as previously described, Brantigan appears to disclose the opposite (i.e., that the implant is "sized to conform with the disc space"). We, therefore, agree with Petitioner that one of ordinary skill in the art would not have understood that Brantigan discloses or suggests that the implant must not extend into the disc space encompassed by the apophyseal ring (not having been disclosed or suggested by Brantigan).

Patent Owner argues that "a figure in Brantigan . . . was admittedly drawn incorrectly." PO Resp. 36 (citing Ex. 2041, 1516:13–25, 1517:6–12; Ex. 2039, 44:5–14). In particular, Patent Owner argues that Figure 11 of Brantigan allegedly contains discrepancies regarding the direction of insertion of the implant into the intervertebral space. *See, e.g.*, Ex. 2041, 1516:13–25. We are not persuaded by Patent Owner's argument at least because, even if Figure 11 discloses discrepancies regarding the direction of insertion of the implant, Patent Owner does not show persuasively that any such errors in Figure 11 sufficiently refute the prima facie case of obviousness that it would have been obvious to one of ordinary skill in the art to have provided an implant sized to occupy "substantially the full transverse widths of the vertebral bodies" given Brantigan's explicit disclosure that the implant is "sized to conform with the disc space."

Patent Owner argues that Brantigan discloses an implant that "can be rotated or reversed and still fit the vertebrae." PO Resp. 37 (citing Ex. 1006, 2:24–25; Ex. 2038 ¶ 113). Given that the implants of Brantigan are inserted "to support and fuse with adjacent vertebrae" (Ex. 1006, 1:65–66), we agree with Petitioner that one of ordinary skill in the art would have understood not to remove an implant once already inserted because doing so would not

have permitted the implant to have provided the support desired or to have fused with adjacent vertebrae, as Brantigan discloses. Thus, we agree that one of ordinary skill in the art would have understood that Brantigan discloses that the implant of Brantigan may be selected to be inserted in any desired orientation (i.e., "rotated or reversed" prior to insertion so that the implant will "still fit the vertebrae").

In any event, regardless of which construction of "rotated or reversed and still fit the vertebrae" is used, as discussed previously, Brantigan discloses that the implant is "sized to conform with the disc space," which one of ordinary skill in the art would have understood to mean sized to occupy substantially the full transverse widths of the vertebral bodies for reasons previously stated.

Patent Owner argues that Brantigan discloses "an anterior approach to the spine," as opposed to a lateral approach. PO Resp. 26. As previously discussed, Jacobson discloses or suggests this feature. We need not determine whether one of ordinary skill in the art would have understood Brantigan to also disclose this feature.

Leu – "interbody intraspinal implant"

Patent Owner argues that Leu discloses a "graft conglomerate" that, according to Patent Owner "is not a spinal fusion implant." PO Resp. 47–48 (citing Ex. 2038 ¶¶ 89; 97–99). Claim 1 recites an "interbody intraspinal implant." Patent Owner's declarant (Dr. Sachs) testifies that Leu discloses that the "graft conglomerate" contains "impacted bone" and "soft cancellous bone" that "is not a structural implant as claimed by the '997 [patent]." Ex. 2038 ¶ 97. Hence, Patent Owner appears to argue that one of ordinary skill

in the art would have understood that an "interbody intraspinal implant," as recited in claim 1, must not contain "impacted bone" or "soft cancellous bone" such that the implant is not a "structural implant."

Patent Owner does not demonstrate that claim 1 recites that the "interbody intraspinal implant" must not contain "impacted bone" or "soft cancellous bone." Nor does Patent Owner indicate that the '997 patent specification discloses this explicit definition of the term. While Patent Owner's declarant (Dr. Sachs) testifies that "this graft conglomerate [of Leu] is not a structural implant as claimed by the '997 [patent]," Ex. 2038 ¶ 97, Petitioner's declarant (Dr. McAfee) testifies that "nothing in Leu's suggestion for the 'porous apatite' graft . . . required an ordinary spinal surgeon . . . to limit his or her thoughts only to 'bits of porous apatites'" and that "spinal surgeons of ordinary skill understood that various non-bone elements were inserted into the disc space as part of conventional interbody fusion." Ex. 1029 ¶ 57. Hence, even if one of ordinary skill in the art would have understood that an "interbody interspinal implant," as recited in claim 1, must have provided structural support and that a "graft conglomerate" containing only "impacted bone" and "soft cancellous bone" would have provided insufficient structural support to be characterized as an "interbody intraspinal implant" (as Dr. Sachs testifies), we credit Dr. McAfee's testimony that one of ordinary skill in the art would have also understood that "non-bone elements were inserted into the disc space as part of conventional interbody fusion," to provide sufficient structural support to be classified as an "interbody interspinal implant."

In any event, Dr. McAfee also testifies that it would have been obvious to one of ordinary skill in the art to have "employ[ed] an implant

structure *having a size/structure suggested by Brantigan* in the resulting surgical method of Jacobson in view of Leu." Ex. 1029 ¶ 57. Hence, Petitioner and Dr. McAfee argue that Brantigan also discloses an "interbody intraspinal implant," as recited in claim 1. Patent Owner does not appear to contest Petitioner's contention.

"Elongated portion"

Patent Owner argues that Jacobson fails to disclose or suggest an "elongated portion" because, according to Patent Owner, "[t]hese portions [as disclosed by Jacobson] are not 'positioned over' adjacent vertebrae." PO Resp. 50. Patent Owner does not demonstrate that any one of claims 1–8 recites an "elongated portion."

Jacobson, Leu, Brantigan - combinability

Patent Owner argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Jacobson, Leu, and Brantigan. PO Resp. 50–53. Jacobson discloses advancing instruments laterally into the disc space to perform a "fusion" procedure. Ex. 1004, 5:1–4, 6:11–13. Leu discloses fusion of the lumbar spine by introducing an "interbody graft" into the disc space. Ex. 1005, p. 603. Brantigan, like Leu, discloses "prosthetic implant devices" that are "suitable for . . . lateral placement in any area of the spine." Ex. 1006, 2:56–58. We agree with Petitioner that the combination of the known element of performing a spinal fusion procedure by laterally advancing instruments into the disc space (Jacobson) with the known element of using an "interbody graft" in a spinal fusion procedure (Leu and Brantigan) would have resulted in no more than

the predictable and expected result of performing a spinal fusion procedure (Jacobson) that includes inserting an implant into a disc space (Leu or Brantigan). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007).

Patent Owner argues that one of ordinary skill in the art would not have combined the teachings of Jacobson with Leu because "the sequential dilators [of Leu] would *widen the perforation* [caused by a needle puncture to the patient's intestines] without any warning to the surgeon." PO Resp. 51. We are not persuaded by Patent Owner's argument at least because none of Jacobson or Leu supports the contention made.

Patent Owner also argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Brantigan with any of Jacobson or Leu because, according to Patent Owner, Brantigan "teaches away from sizing an implant to rest on the apophyseal ring or be sized to occupy substantially the full transverse width of adjacent vertebral bodies." PO Resp. 51–52, 55–56. This issue was discussed previously above.

Patent Owner also argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Brantigan with any of Jacobson or Leu because the "cannulae disclosed by Jacobson and Leu are too narrow to accommodate Brantigan's implant," that "a person of ordinary skill in the art would not be able to insert [Brantigan's] implant in Jacobson's [system]," and that "the shape of the Brantigan implant is not conducive to insertion through a cannula or similar surgical instrument [as disclosed by Jacobson or Leu]." PO Resp. 52. In other words, Patent

Owner argues that the combination of Jacobson, Brantigan, and Leu would not have been obvious to one of ordinary skill in the art because the prior art systems are not physically combinable (i.e., Brantigan's implant allegedly cannot be physically combined with the cannula of either Jacobson or Leu). "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference . . . . Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981); *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."). We are thus not persuaded by Patent Owner's argument.

Secondary considerations

We recognize that evidence of secondary considerations must always be considered en route to the determination of obviousness, but its existence alone does not control the conclusion of obviousness. *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). The weight given to evidence of secondary considerations is dependent upon whether there is a nexus between the merits of the claimed invention and the evidence offered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983).

Commercial Success

Patent Owner argues non-obviousness based on alleged commercial success of the claimed invention. PO Resp. 56–57. Patent Owner contends that Petitioner's product (i.e., the "XLIF procedure and CoRoent XL

implants") and Patent Owner's product (i.e., the "DLIF procedure and Clydesdale and Capstone L implants") have "enjoyed tremendous commercial success," based on "100,000 spinal levels" having been treated since 2003, sales of Petitioner's product of "$250M from May 2004 to June 2010," and sales of Patent Owner's product of over "$50M over approximately the same time period." PO Resp. 56–57 (citing Ex. 2038 ¶ 136; Ex. 2045, 47; Ex. 2046–2048).

Even assuming the sales figures quoted by Patent Owner for both Petitioner's product and Patent Owner's product are correct, and assuming that these sales figures represent "commercial success," Patent Owner has not demonstrated a sufficient nexus between the merits of the claimed invention and the evidence offered. Patent Owner contends that "in order to encourage surgeons to select its product, Petitioner touts the CoRoent XL implant as having the patent features of the '997 patent, such as a 'large foot print,' 'spans ring apophysis,' and 'maximizes fusion surface area.'" PO Resp. 57 (citing Ex. 2049, 21). We note that Patent Owner does not show that any of "large foot print," "spans ring apophysis," or "maximizes fusion surface area" is recited in the claims of the '997 patent. Not having identified any specific features in the claims of the '997 patent that form the basis for the commercial success of Petitioner's product, Patent Owner does not show persuasively a nexus between the claimed invention and the evidence proffered.

In addition, even assuming that these features are recited in the claims of the '997 patent, Patent Owner still does not demonstrate a sufficient nexus between these specific alleged features and the evidence relied upon to demonstrate commercial success (i.e., sales figures). Upon review of the

marketing materials cited by Patent Owner, we observe that in addition to a "large foot print," "spans ring apophysis," and "maximizes fusion surface area," the marketing materials also allege other benefits of the marketed product such as "minimal soft tissue/muscle damage," "reduced post-operative morbidity," "outpatient or 23 hr procedure," "adequate exposure," "safe and reproducible," and "meet or exceed traditional results." Ex. 2049, 17. Patent Owner provides insufficient evidence to show which of these alleged benefits of the marketed product (if any) would have resulted in (i.e., had a "nexus" to) the "commercial success" (i.e., sales revenue) alleged by Patent Owner.

Industry Praise

Patent Owner argues non-obviousness based on "industry praise" allegedly attributed to the claimed invention. PO Resp. 58-59. Industry praise must also be linked to the patented invention. *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1352 (Fed. Cir. 2010). Patent Owner cites to "Back.com," in which Dr. Richard Hynes states the benefits of the DLIF [Direct Lateral Interbody Fusion] procedure are that "you're approaching the disc from the side rather than from the front or back." Ex. 2050, p. 3. Petitioner has demonstrated that this feature (i.e., "direct lateral" approach), as discussed above, is disclosed by Jacobson. Hence, the feature that is allegedly praised was already present in the prior art. Under those circumstances, any evidence of secondary considerations stems from what was known in the prior art, so that there can be no nexus. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011) ("If [secondary considerations are] due to an element in the prior art, no nexus exists.").

Dr. Hynes alleges additional benefits of DLIF including "a very small, 1-2 cm incision," no "big incisions," no "cutting through muscles," "patients were in and out of the OR in less than an hour," and there was "major stabilization with no blood loss." Ex. 2050, p. 3. Patent Owner does not demonstrate sufficiently that any of these additional allegedly praiseworthy features are recited in the '997 patent claims. Hence, Patent Owner fails to demonstrate sufficiently a nexus between the alleged praise and the claimed invention.

Patent Owner also cites to Rose Mary Budge, "A New Solution," 2004–2009, available at http://www.spinaldoc.com/NuVasive_Spinal_Surgery.php. ("Budge," Ex. 2051). Budge discloses the procedure "involves side entry to the surgical [site] rather than from the back or the front." Ex. 2051 at 1. As previously described, this "praise," to the extent that this objective statement of the direction of entry to the surgical site can be considered "praise" at all, was known in the prior art (e.g., Jacobson), so that there can be no nexus. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011).

Budge further states other benefits of the procedure, including that the procedure is "less intimidating than the traditional methods," "can significantly lessen collateral damage," causes "less tissue trauma, less scarring, less blood loss and less post-operative discomfort." Ex. 2051 at 1. As previously described, Patent Owner does not show sufficiently a nexus between any of these additional allegedly praiseworthy features and the claimed invention because Patent Owner does not demonstrate that any of these features are recited in the claims of the '997 patent.

Patent Owner also cites to PR Newswire, "26 Technologies Receive 2009 Spine Technology Awards," 2009 ("PR Newswire," Ex. 2052) as demonstrating that "Petitioner's XLIF was selected as a 'Best New Technology for 2009' by Orthopedics This Week, an industry publication, and won an award in the "Minimally Invasive Care' category." PO Resp. 58. Even assuming that the "XLIF" won an award as Patent Owner asserts, Patent Owner does not show sufficiently that this award (or praise) had a nexus to a claim feature of the '997 patent (or which claim feature that might be).

Patent Owner further argues that Dr. Michelson testifies that Mr. Larry Boyd (presumably an officer at Sofamor Danek) had, for the first time, "seen a lateral retroperitoneal [approach]" at some point in time. PO Resp. 59 (citing Ex. 2041, 195:24 – 196:2). According to Patent Owner, officers at Sofamor Danek were "'very excited' about Dr. Michelson's technology and moved quickly to acquire it by signing a license agreement." PO Resp. 59 (citing Ex. 2041, 68:7–15). Patent Owner does not provide sufficient evidence explaining what features caused officers at Sofamor Danek to become "very excited" or why the officers allegedly "moved quickly" to sign a license agreement or how any alleged excitement or speed in the signing of license agreements pertains to specific features recited in claims 1–8. Hence, Patent Owner does not show a sufficient nexus between the claimed invention and the activities alleged to constitute "praise."

Copying

Patent Owner argues non-obviousness based on alleged copying of the claimed invention by competitors. PO Resp. 59–60. "[C]opying by a

competitor may be a relevant consideration in the secondary factor analysis." *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) (citing *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed.Cir.1984). "[A] nexus between the copying and the novel aspects of the claimed invention must exist for evidence of copying to be given significant weight in an obviousness analysis." *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012) (internal quotation omitted). Copying as objective evidence of nonobviousness requires evidence of effort to replicate a specific product. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Iron Grip*, 392 F.3d at 1325. Generally, evidence of alleged copying may be given little weight when the copy is not identical to the product embodying the claimed invention. *See Pentec, Inc. v. Graphic Controls, Corp.*, 776 F.2d 309, 317 (Fed. Cir. 1985).

Patent Owner asserts that Petitioner "worked on an early lateral access project called 'ELIF,' which stood for Extreme Lateral Interbody Fusion," trademarked the term "XLIF—for eXtreme Lateral Interbody Fusion" for the product, and eventually "evolved into a profitable company." PO Resp. 60 (citing Ex. 2041, 329:14–25, 434:2 – 435:14, 573:9 – 574:5, 979:19 – 24). Patent Owner also states that "prototypes created by Dr. Michelson included an implant with a 42 mm length, a distractor, outer sleeve, and other instruments." PO Resp. 60 (citing Ex. 2004). Patent Owner does not demonstrate sufficiently that the alleged copy (i.e., "ELIF" or "XLIF") is identical to the product embodying the claimed invention. Therefore, little weight is accorded to Patent Owner's allegations of copying. To the extent that Patent Owner argues that the "ELIF" or "XLIF" systems utilize implants

measuring 42 mm in length, a distractor, outer sleeve, and "other instruments," Patent Owner does not demonstrate that such a system embodies the claimed invention. For example, Patent Owner does not show that any of the claims of the '997 patent recite that the implant measures 42 mm in length and does not explain what the "other instruments" entail.

We have considered the evidence presented, but do not discern that it adequately establishes that the pertinent products are replications of a product that includes all the features of claim 1 of the '997 patent. In any event, even assuming that the noted "ELIF" or "XLIF" products do incorporate all the features of claim 1, it is not the case that "every competing product that arguably falls within the scope of a patent is evidence of copying." *IronGrip*, 392 F.3d at 1325. Rather, as noted above, copying requires the "replication" of a specific product. *Id*.

Patent Owner does not provide additional arguments or evidence with respect to claims 2–8. Petitioner has shown by a preponderance of the evidence that claims 1 and 8 are unpatentable over the combination of Jacobson, Leu, and Brantigan and that claims 2–7 are unpatentable over the combination of Jacobson, Leu, Brantigan, and Frey.

B. Grounds Based at least in part on Jacobson, Leu, and Michelson '247

Claim 1 recites the length of an implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae. Michelson '247 discloses "an artificial fusion implant to be placed into the intervertebral space left after the removal of a damaged spinal disc" in which a drill is used that is "such a length that it can not penetrate more than **28** millimeters beyond the end of the drill sleeve" so

that "the implant . . . is able to be inserted only 28 millimeters." Ex. 1008, 1:5–7; 9:40–42; 10:31–32. Michelson '247 also discloses that "the implant . . . is only 26 millimeters in length . . . [which] guarantees that the implant . . . will be recessed into the vertebral bodies more than 2 millimeters and can not protrude into the spinal canal." Ex. 1008, 10:32–36. While Michelson '247 discloses an implant that measures 26 millimeters in length and is inserted into a drilled opening that is 28 millimeters in length, Petitioner does not demonstrate sufficiently that Michelson '247 also discloses that the implant must occupy substantially the full transverse width of the vertebral body (as recited in claim 1). For example, Michelson '247 merely discloses a specific length of 26 millimeters for the length of the implant (26 millimeters) and a specific length of a drilled opening (28 millimeters), but does not disclose the length of the implant (or opening) in relation to the size of the vertebral body.

Michelson '247 further discloses that the drill may be "varied and made smaller for enhanced safety," but does not appear to disclose elongating the drill to a length greater than 28 millimeters. Ex. 1008, 9:42–43. That further demonstrates that Michelson '247 fails to disclose or suggest sizing the implant to obtain the maximum sized implant with respect to the size of the vertebral body. Instead, Michelson '247 appears to suggest using only smaller sized implants "for enhanced safety."

Petitioner argues that Michelson '247 discloses that the implant "should extend longitudinally across the full disc space in the axial direction of insertion." Pet. 11. As Patent Owner points out, "there is ***nothing in the written disclosure*** of Michelson '247 that teaches a surgeon to size an implant to span as much of the length as possible from an anterior to

posterior direction." PO Resp. 41 (citing Ex. 2039, 44:16–19; 45:6–16). Petitioner does not point out where specifically Michelson '247 discloses or suggests this feature.

Petitioner argues that Patent Owner does not argue Michelson '247 discloses an implant that would not rest on the apophyseal ring or that the implant is designed to rest only on a spongy center part of the vertebrae and that "the '997 patent's drill has the very same feature [as the drill disclosed by Michelson '247]." Pet. Reply 11. Even assuming Petitioner's allegations to be correct, Petitioner still does not demonstrate persuasively that Michelson '247 discloses or suggests an "implant being sized to occupy substantially the full dimension of the vertebral body, as recited in claim 1.

Claims 2–8 depend from claim 1. Petitioner does not allege that any of Jacobson, Leu, or Alacreu discloses or suggests the disputed feature. Petitioner has not demonstrated by a preponderance of the evidence that that claims 1-8 would have been obvious over the combination of Jacobson, Leu, and Michelson '247 (and Alacreu).

C. Motion to Exclude

In its Motion to Exclude, Patent Owner seeks to exclude the following documents:

1. Declaration of Dr. Paul McAfee ("McAfee Declaration," Ex. 1001, 54–85);
2. Affidavit of Henry Vernon Crock (Ex. 1020–1026);
3. Second Declaration of Dr. Paul McAfee (Ex. 1029 ¶¶ 4, 7, 9, 10, 37–39, 43–45, 48, and 49);
4. Declaration of Dr. Robert E. Jacobson ("Jacobson Declaration," Ex. 1030 ¶¶ 4–6, 8, and 10);

5. Declaration of Patrick Miles ("Miles Declaration," Ex. 1032 ¶ 9);
6. William A Friedman, *Percutaneous Discectomy: An Alternative to Chemonucleolysis?*, NEUROSURGERY, Vol. 13, No. 5 (1983) ("Friedman Article," Ex. 1036);
7. Steven L. Kanter and William A. Friedman *Percutaneous Discectomy: An Anatomical Study*, NEUROSURGERY, Vol. 16, No. 2 (1985) ("Kanter Article," Ex. 1037);
8. Medtronic Corporate Structure (Ex. 1046);
9. Gregory M. Malham, et al., *Clinical Outcome and Fusion Rates after the First 30 Extreme Lateral Interbody Fusions*, THE SCIENTIFIC WORLD JOURNAL (2012) ("Malham Article," Ex. 1049);
10. Armen R. Deukmedjian, "Bowel and Vascular Injury Following 13,000 Lateral Interbody Fusions," SMISS 2013 ANNUAL CONFERENCE ("Deukmedjian Article," Ex. 1050); and
11. Paul C. McAfee, et al., *Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine*, SPINE, Vol. 23, No. 13 (1998) ("McAfee Article," Ex. 1067).

For the reasons discussed below, the motion is dismissed.

Second Declaration of Dr. Paul McAfee – Ex. 1029 ¶ 38

Patent Owner alleges that the Second Declaration of Dr. Paul McAfee (Ex. 1029 ¶ 38) should be excluded because, according to Patent Owner, "Dr. McAfee wrongly relies on Dr. Jacobson's declaration (Exhibit 1030) about the alleged surgeries he performed prior to 1995," that "Dr. McAfee wrongly relies on the Crock Affidavit (Exhibit 1014) in paragraphs 7 and 9 of his second declaration about the surgeries Dr. Crock allegedly performed

prior to 1995," which, according to Patent Owner, "are not relevant to whether the challenged claims are unpatentable in light of the prior art patents and printed publications in the instituted claims." Paper 50 at 6.

The Second Declaration of Dr. Paul McAfee, however, is not relied upon for any alleged surgeries performed by Dr. Crock or Dr. Jacobson prior to 1995 (or at any other time). Rather, the Second Declaration of Dr. Paul McAfee is relied upon to support what one of ordinary skill in the art would have understood based on Figure 6 of the '997 patent at the time of the invention (see above). Ex. 1029 ¶ 38. Thus, we are not persuaded that the Second Declaration of Dr. Paul McAfee (at ¶ 38) should be excluded.

Jacobson Declaration – Ex. 1030 ¶ 5

Patent Owner moves to exclude the Jacobson Declaration (Ex. 1030 ¶ 5) based on various bases. Patent Owner alleges that the Jacobson Declaration (Ex. 1030 ¶ 5) "include[s] what Dr. Jacobson was allegedly ***doing*** prior [to] 1995, not what the Jacobson '374 reference discloses to a person of ordinary skill in the art." Paper 50, 9–10.

The Jacobson Declaration (Ex. 1030 ¶ 5) is relied upon to ascertain what one of ordinary skill in the art would have understood by the term "lateral" and "direct lateral" at the time of the invention (see above) and is not relied upon for any procedures Dr. Jacobson may or may not have been alleged to have performed prior to 1995. Thus, we are not persuaded that the Jacobson Declaration (at ¶ 5) should be excluded.

Other Evidence

As previously described, Patent Owner moves to exclude other evidence, none of which was relied upon by the Board. Therefore, Patent Owner's motion to exclude is moot with respect to the other evidence.

ORDER

Petitioner has demonstrated, by a preponderance of the evidence, that claims 1 and 8 are unpatentable over Jacobson, Leu, and Brantigan under 35 U.S.C. § 103(a) and that claims 2–7 are unpatentable over Jacobson, Leu, Brantigan, and Frey. Petitioner has not demonstrated, by a preponderance of the evidence, that claims 1–8 are unpatentable over Jacobson, Leu, and Michelson '247 (and Alacreu) under 35 U.S.C. § 103(a).

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–8 of the '997 patent have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *dismissed*.

This is a final decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2013-00208
Patent 8,251,997 B2

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Paper 67
Date: August 28, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

WARSAW ORTHOPEDIC, INC.,
Patent Owner.

Case IPR2013-00206
Patent 8,251,997 B2

Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges.*

SIU, *Administrative Patent Judge*.

DECISION
Petitioner's Request for Rehearing
37 C.F.R. § 42.71(d)

I. BACKGROUND

NuVasive, Inc. ("Petitioner") requests reconsideration of the Board's final written decision ("Decision" or "Dec."), dated July 10, 2014 (Paper 65). In the Decision, we determined that Petitioner has not shown by a preponderance of the evidence that claims 9–16 and 24–30 of US Patent No. 8,251,997 B2 ("the '997 patent"), which is assigned to Warsaw Orthopedic, Inc. ("Patent Owner"), are unpatentable. Dec. at 36.

We have considered Petitioner's request, but we decline to modify the final written decision.

II. STANDARD OF REVIEW

A party challenging a final written decision by way of a request for rehearing must identify specifically all matters the party believes the Board misapprehended or overlooked. 37 C.F.R. § 42.71(d). The challenging party bears the burden of showing that the decision should be modified. *Id*.

III. DISCUSSION

Claim 9 recites "the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae." Petitioner argues that we "overlook[ed] or misapprehend[ed] the clear teachings of Michelson '247 (particularly Figure 5 and col. 5, lines 1-7)" in concluding that Michelson '247 fails to disclose or suggest this feature. Req. Reh'g. 3. We disagree with Petitioner.

Michelson '247 discloses that "the present invention offers . . . greater surface area [as compared to the BAGBY device] to distribute the load" and is

"placed bilaterally where the bone tends to be more cortical and much stronger." Ex. 1008, 5:2-7. Contrary to Petitioner's contention, Michelson '247 merely discloses a device with greater surface area than the "BAGBY device" and that the device is placed bilaterally. Petitioner does not show sufficiently that Michelson '247 also discloses that the implant is sized to occupy substantially the full transverse width of the vertebral bodies. Regarding Figure 5, we note that Michelson '247 merely discloses that Figure 5 is "a sectional view of the vertebra structure, taken along lines 5—5 of FIG. 4." Ex. 1008, 7:61-62. Petitioner does not show sufficiently that Michelson '247 discloses that Figure 5 is drawn to scale or any specific measurements of the components illustrated therein. "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." *Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000) (citing *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977)).

As previously discussed in the Decision, Michelson '247 discloses "an implant that measures 26 millimeters in length [that] is inserted into a drilled opening that is 28 millimeters in length." Decision 32. Petitioner does not show persuasively that Michelson '247 discloses that the device is sized at 26 millimeters or that the drilled opening is sized at 28 millimeters in order to be sized to occupy substantially the full transverse width of the vertebral bodies. In fact, Michelson '247 does not disclose the size of the vertebral bodies at all. Hence, Michelson '247 does not disclose or suggest that the implant is sized to occupy substantially the full transverse width of the vertebral bodies. At best, Michelson '247 merely discloses that the implant is sized to measure 26 millimeters without regard to the size of the vertebral bodies, as previously explained in the Decision.

Petitioner argues that Michelson '247 discloses that "**the present device is placed bilaterally <u>where the bone tends to be more cortical and much stronger out towards the rim</u>**." Req. Reh'g. 4. Petitioner contends that this disclosure indicates that Michelson '247 discloses an implant that is sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, as recited in claim 9. We disagree. Rather, Michelson '247 discloses that a device is placed bilaterally, which refers to the location at which the device is placed (i.e., bilaterally) and does not refer to the size of device (i.e., whether the device is sized to occupy substantially the full transverse width of the vertebral bodies or not).

Petitioner further argues that the Decision overlooks or misapprehends that the combination of Michelson '247 and Jacobson discloses or suggests an implant sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, as recited in claim 9. Req. Reh'g. 6-8. In particular, Petitioner argues that "Jacobson supplies the teaching of the lateral approach." Req. Reh'g. 7. As described in the Decision and reiterated above, Michelson '247 fails to disclose or suggest an implant sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae. Petitioner does not contend that Jacobson discloses or suggests an implant sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae. Hence, Petitioner has not shown sufficiently how either Michelson '247 or Jacobson discloses or suggests this claim feature. Petitioner does not explain sufficiently how this feature would have been obvious to one of ordinary skill in the art in view of the lack of such a suggestion in any of the cited references.

Petitioner further argues that claim 9 would have been obvious to one of ordinary skill in the art given that Michelson suggests the use of "**a longer**

threaded fusion implant" and that "a fusion implant . . . should extend long enough to rest on the cortical bone towards the outer rim." Req. Reh'g. 8, 11. However, Petitioner does not demonstrate sufficiently that Michelson '247 discloses or suggests these features. Rather, Michelson '247 appears to disclose merely an implant measuring 26 millimeters in length that is inserted into a drilled opening that is 28 millimeters in length. In any event, claim 9 recites the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae. Claim 9 does not recite "a longer threaded fusion implant" or an implant that "extends long enough to rest on the cortical bone towards the outer rim." Thus, even assuming that Michelson '247 discloses or suggests a longer threaded fusion implant that extends long enough to rest on the cortical bone towards the outer rim, we are still not persuaded by Petitioner's argument.

Claim 24 recites the length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae. In the Decision, we concluded that Petitioner did not "assert or demonstrate sufficiently that Michelson '247 discloses or suggests an implant sized to occupy the *full* transverse width of the vertebral bodies." Decision 32–33. Petitioner argues that "under a broadest reasonable construction standard [the term "full transverse width," as recited in claim 24, should be construed] to be the same as the phrase 'substantially the full transverse width' in claim 9." Req. Reh'g. 13. We need not further consider Petitioner's proposal to construe the term "full" (as recited in claim 24) to mean "substantially full" because Petitioner does not show persuasively that the asserted combination of references discloses or suggests an implant being sized to occupy either the full width (claim 24) or substantially the full transverse width of the vertebral bodies, as recited in claim 9.

Petitioner does not provide additional arguments in support of claims 10-16 or 25-30.

IV. CONCLUSION

For at least the reasons given, we determine that Petitioner has not carried its burden of demonstrating that the Board misapprehended or overlooked any matters in rendering the final written decision. We decline to modify the final written decision.

V. ORDER

Accordingly, it is

ORDERED that the request for rehearing is denied.

IPR2013-00206
Patent 8,251,997 B2

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US008251997B2

(12) **United States Patent**
Michelson

(10) **Patent No.: US 8,251,997 B2**
(45) **Date of Patent: Aug. 28, 2012**

(54) **METHOD FOR INSERTING AN ARTIFICIAL IMPLANT BETWEEN TWO ADJACENT VERTEBRAE ALONG A CORONAL PLANE**

(75) Inventor: **Gary Karlin Michelson**, Venice, CA (US)

(73) Assignee: **Warsaw Orthopedic, Inc.**, Warsaw, IN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/306,583**

(22) Filed: **Nov. 29, 2011**

(65) **Prior Publication Data**

US 2012/0071984 A1 Mar. 22, 2012

Related U.S. Application Data

(60) Continuation of application No. 10/371,757, filed on Feb. 21, 2003, now Pat. No. 8,066,705, which is a continuation of application No. 08/480,461, filed on Jun. 7, 1995, now Pat. No. 7,491,205, which is a division of application No. 08/394,836, filed on Feb. 27, 1995, now Pat. No. 5,772,661.

(51) **Int. Cl.**
A61F 17/56 (2006.01)

(52) **U.S. Cl.** **606/53**; 606/60; 606/246

(58) **Field of Classification Search** ..... 606/53, 606/60, 86 A, 246–250, 61; 623/16, 17
See application file for complete search history.

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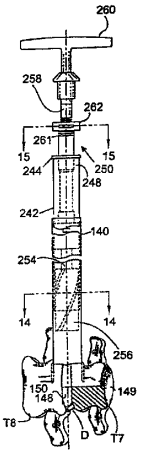
(57) **ABSTRACT**

A method for inserting an artificial implant between two adjacent vertebrae along a coronal plane.

30 Claims, 14 Drawing Sheets



NUVASIVE 1002

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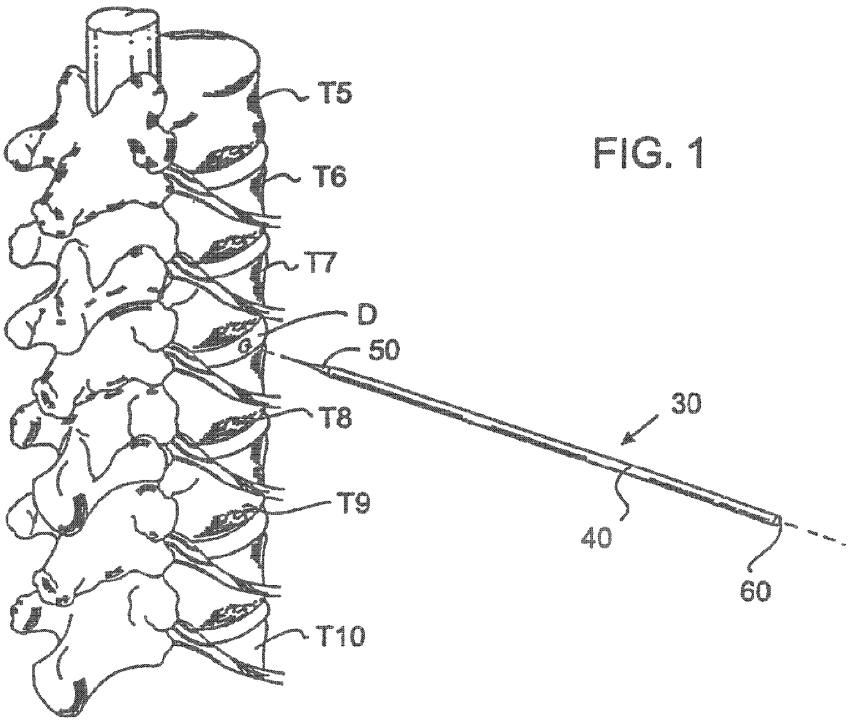
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FIG. 1

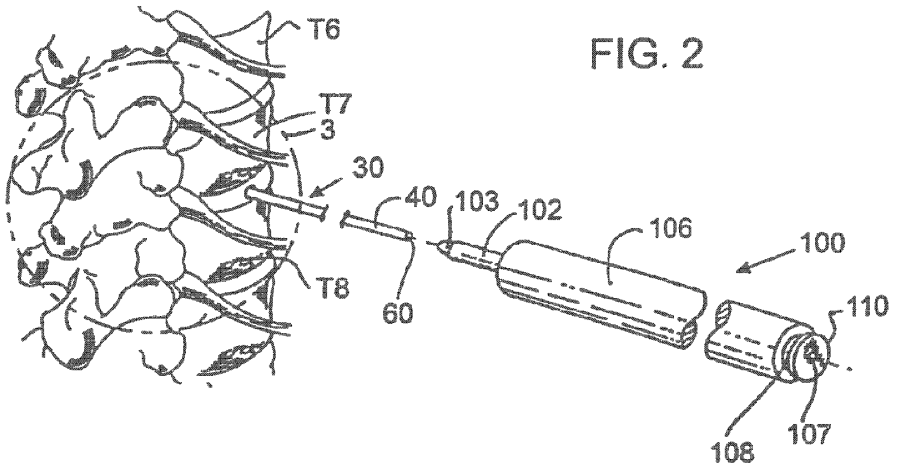
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FIG. 2

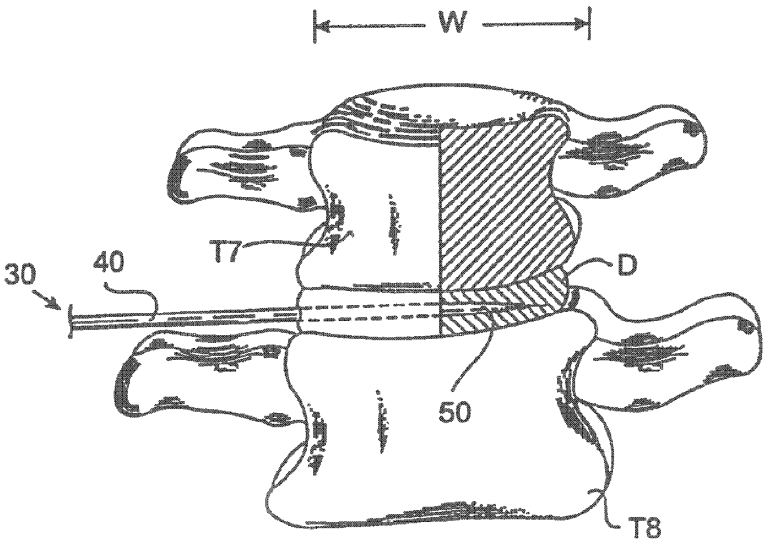

FIG. 3

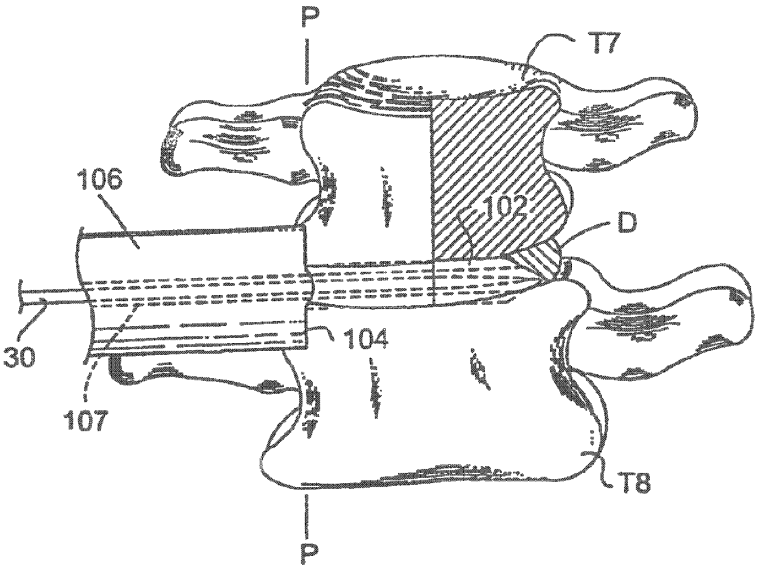

FIG. 4

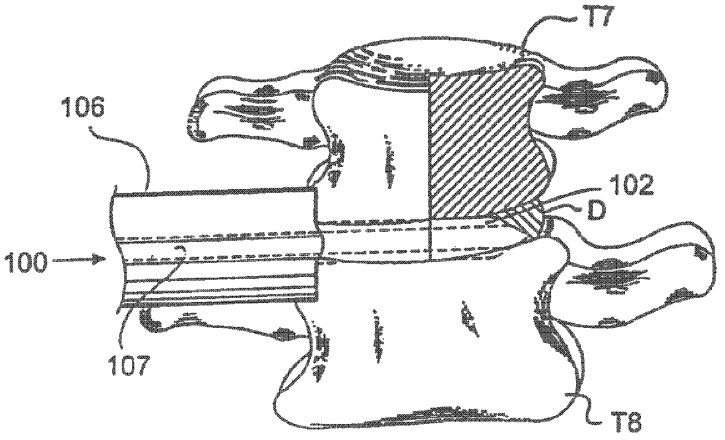

FIG. 5

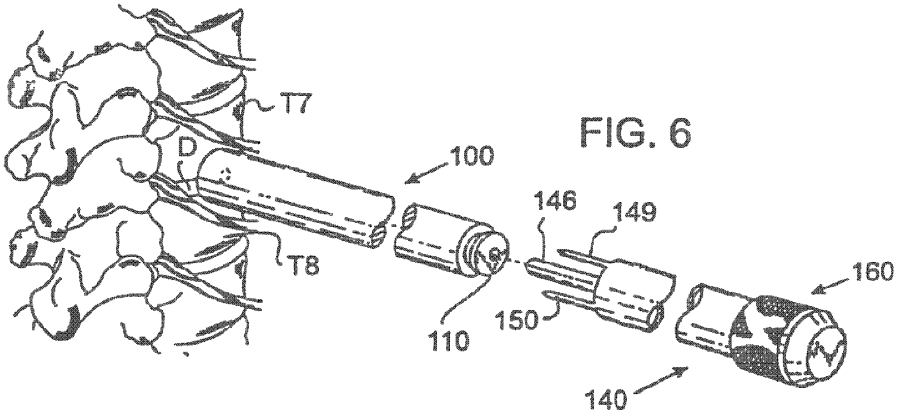

FIG. 6

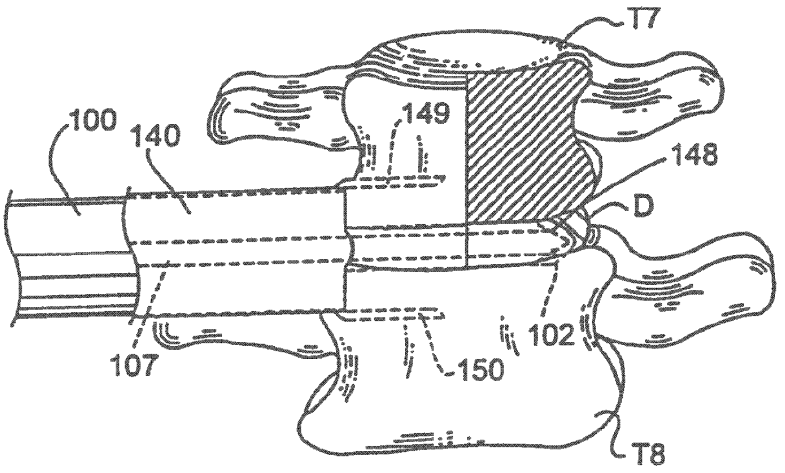

FIG. 7

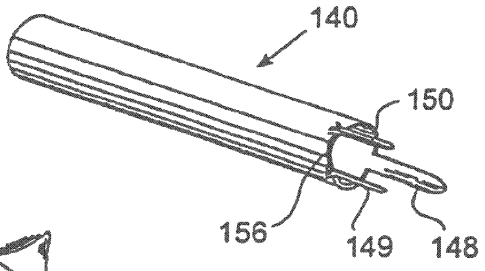

FIG. 7A

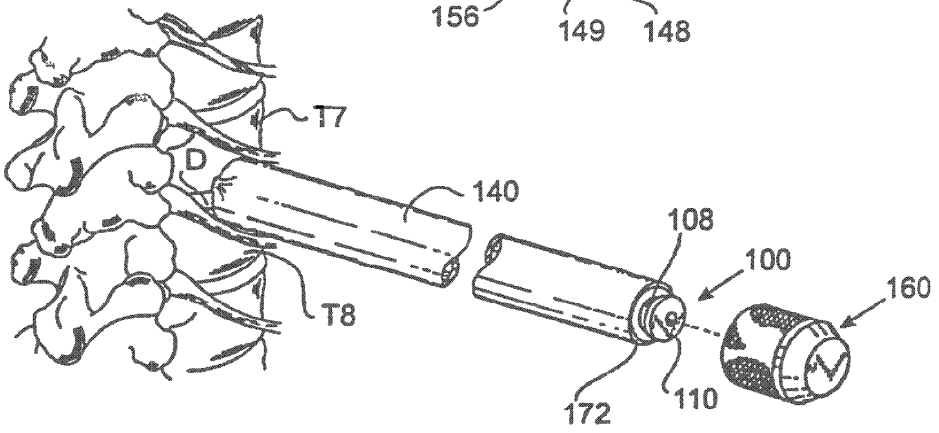

FIG. 8

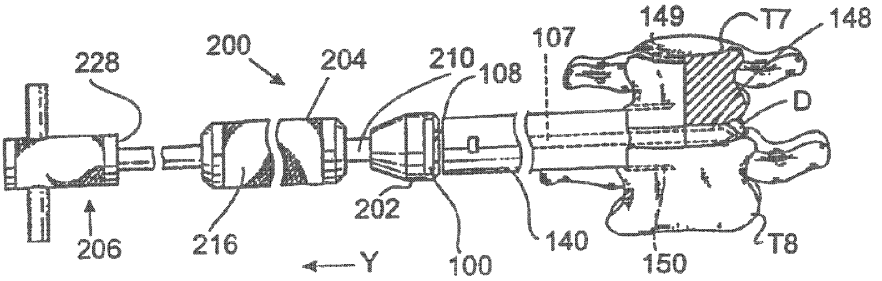
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FIG. 9

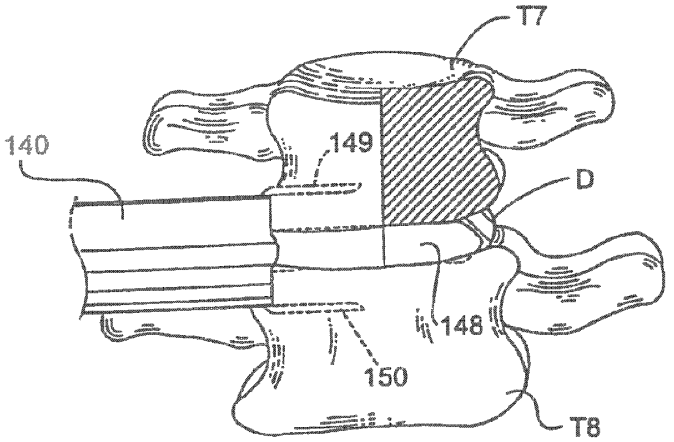
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FIG. 10

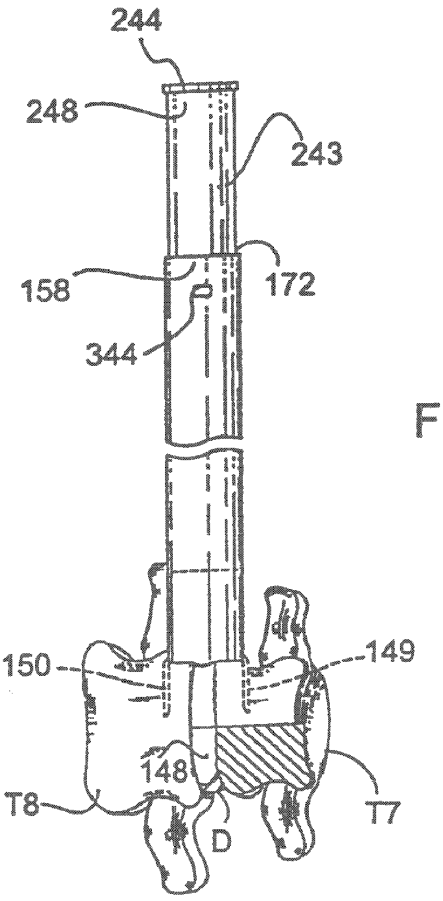
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FIG. 11

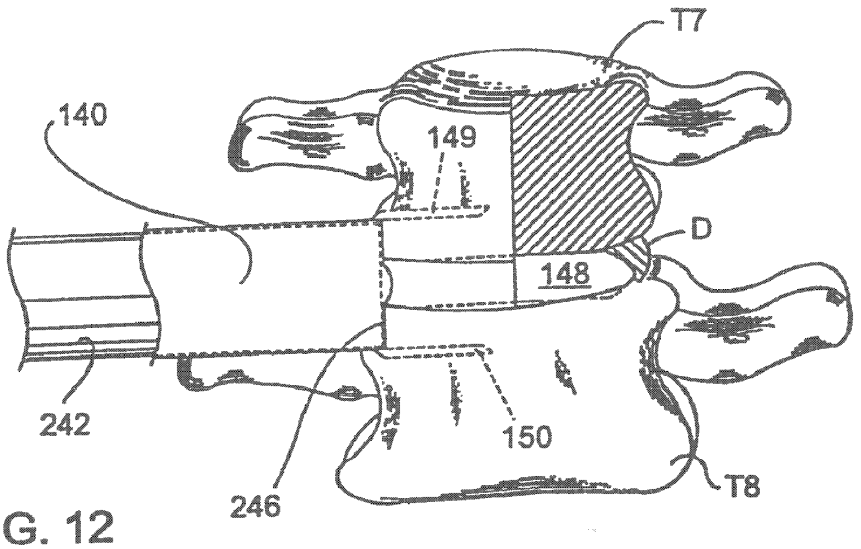
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FIG. 12

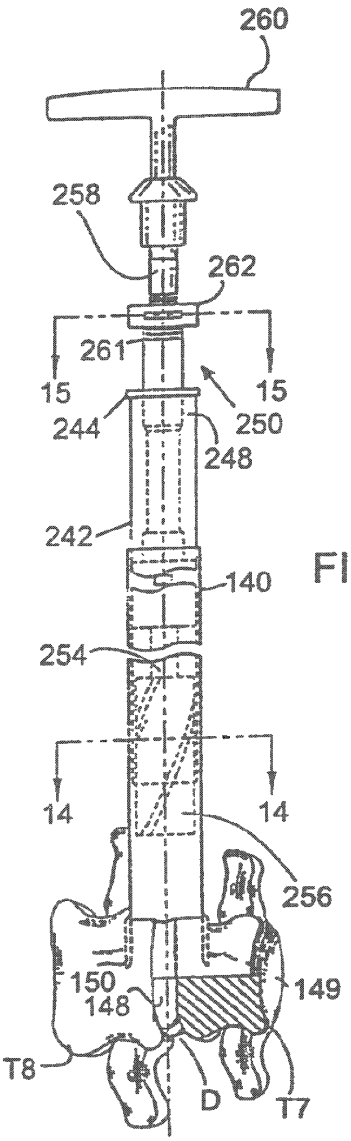

FIG. 13

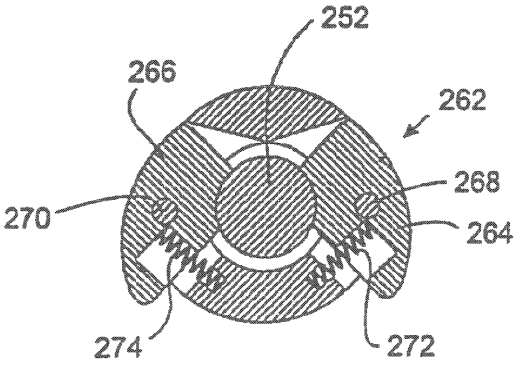

FIG. 15

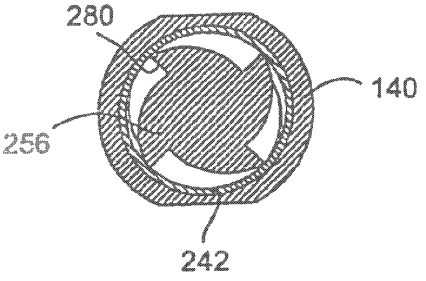

FIG. 14

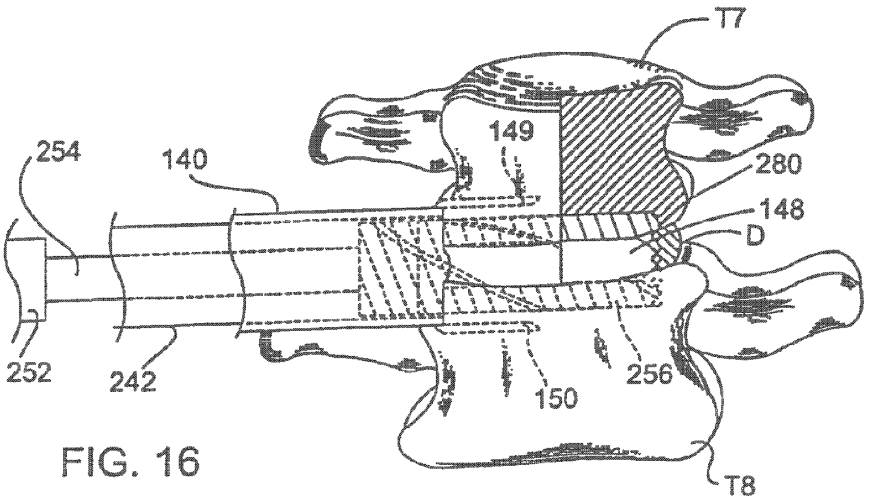
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FIG. 16

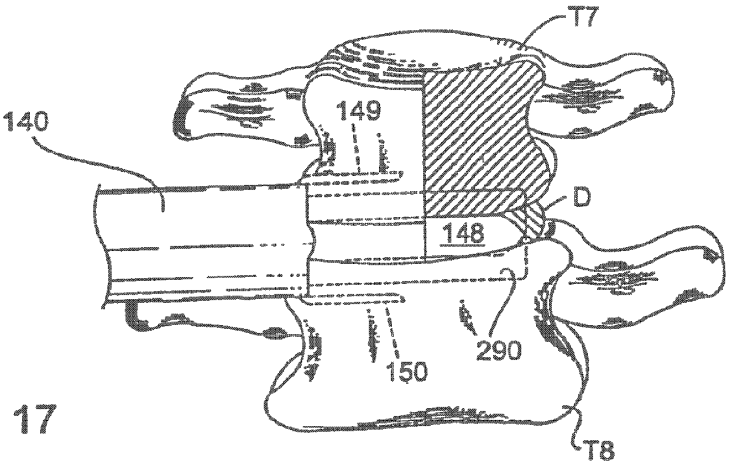
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FIG. 17

FIG. 18

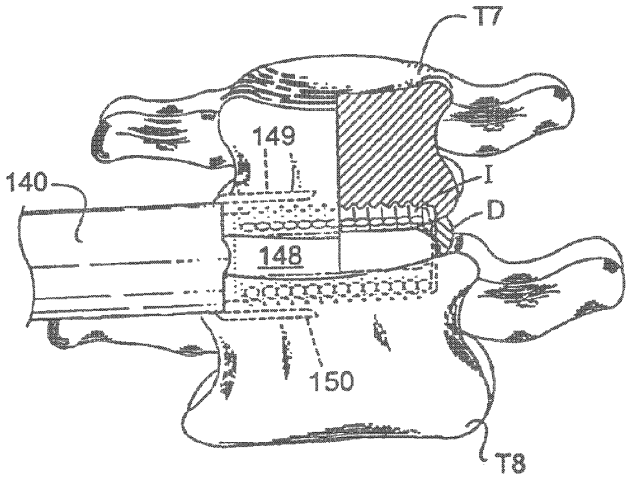
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FIG. 19

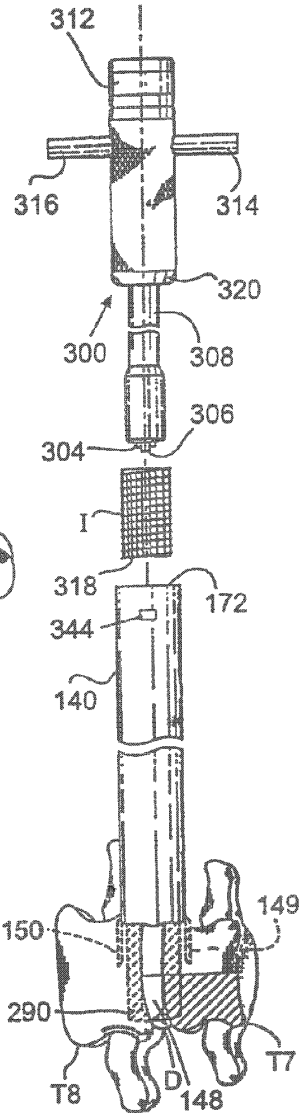
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FIG. 21

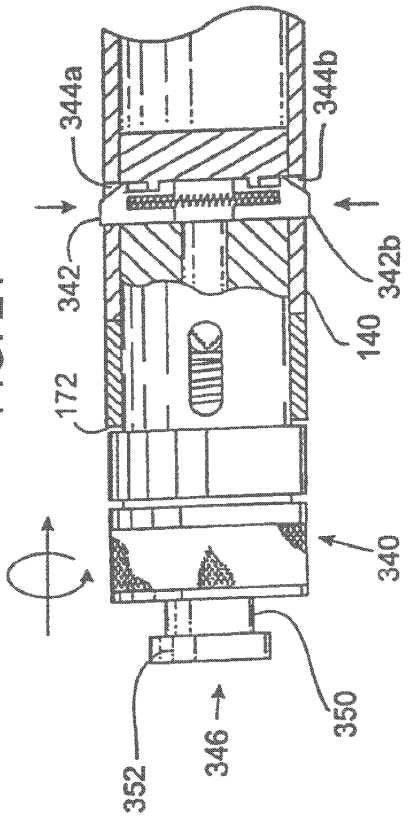
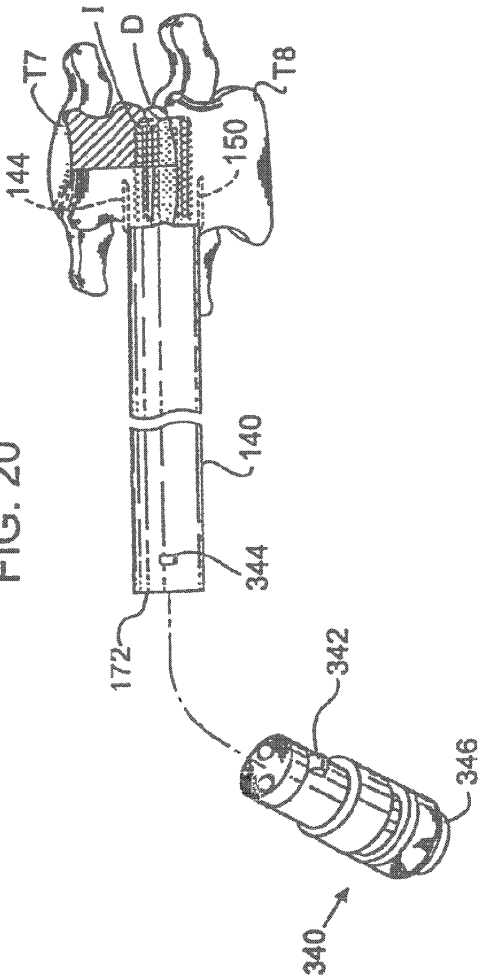

344a
344b
342
342b
140
172
340
350
346
352

FIG. 20


I
D
T7
T8
144
150
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344
172
342
346
340

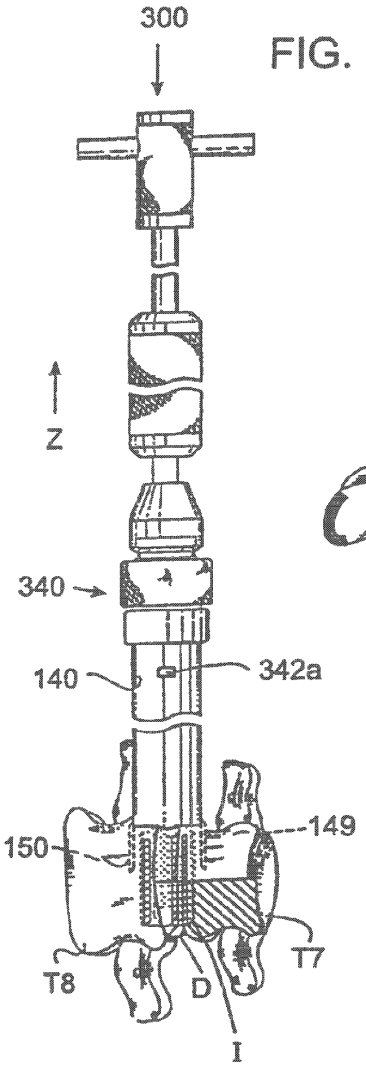


FIG. 22

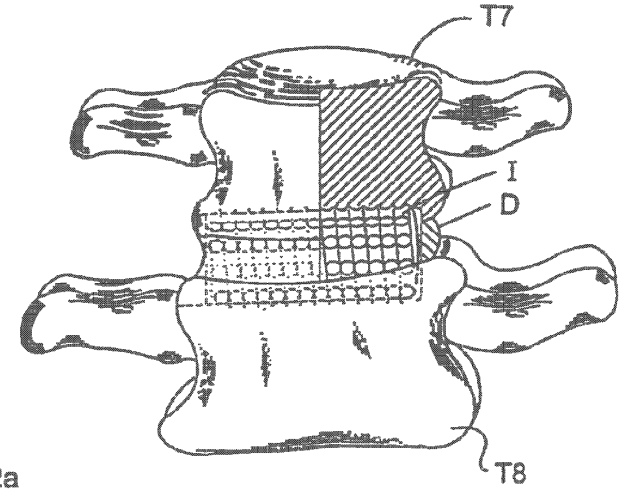


FIG. 23

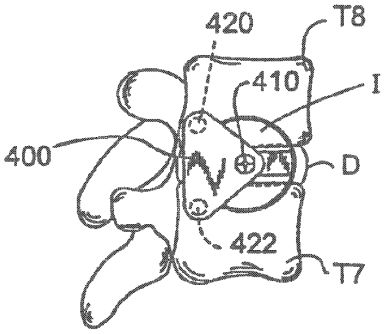


FIG. 24

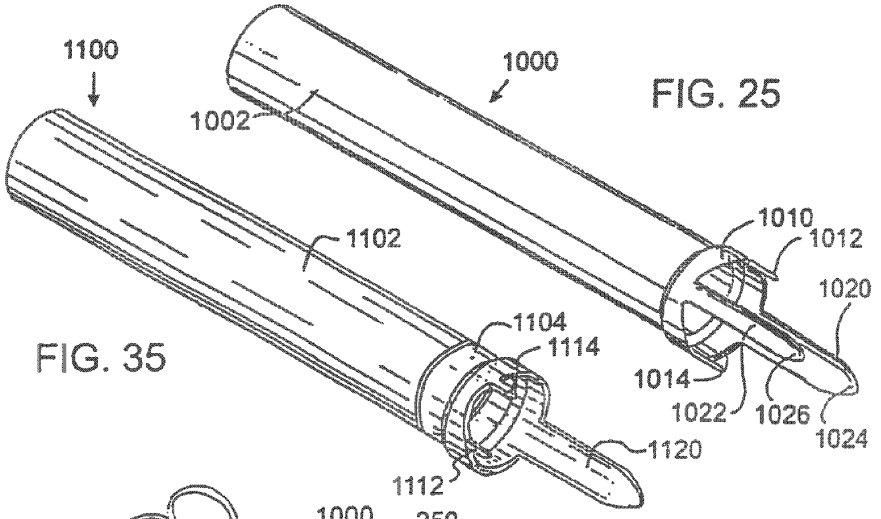


FIG. 35

FIG. 25

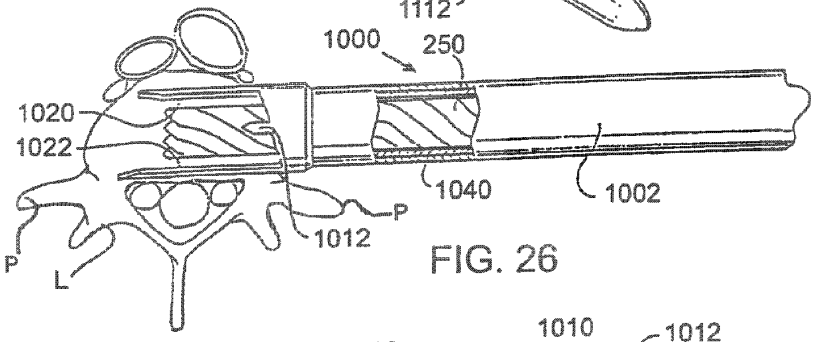


FIG. 26

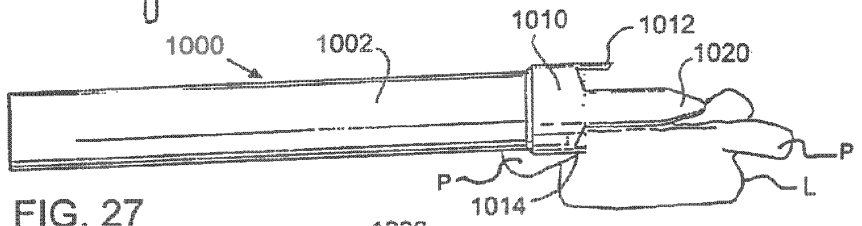


FIG. 27

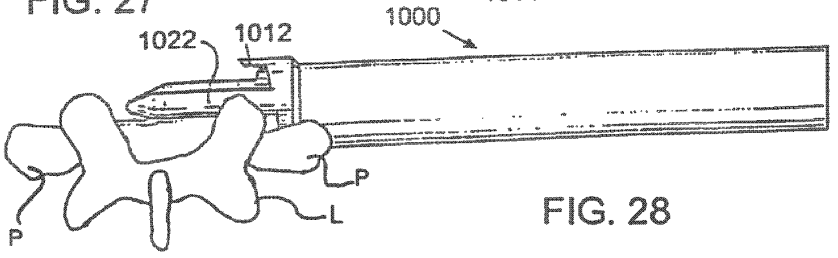
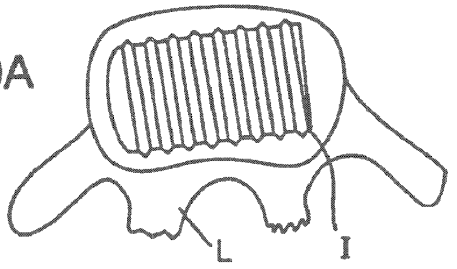


FIG. 28

FIG. 30A



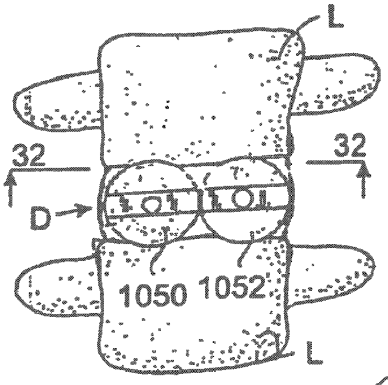


FIG. 31

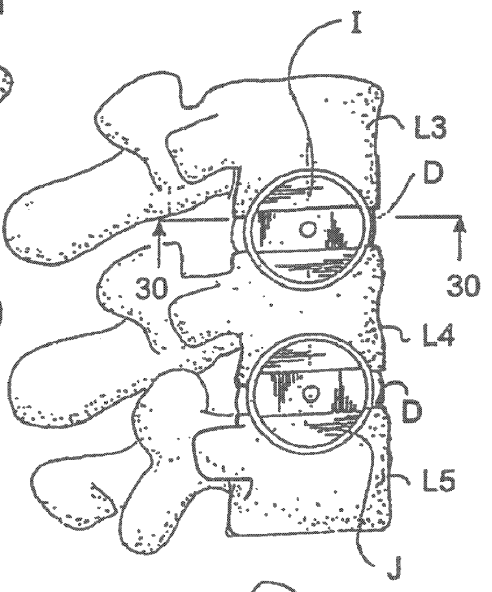


FIG. 29

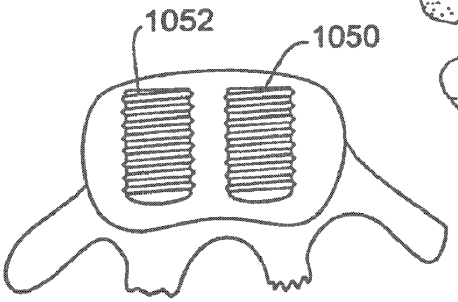


FIG. 32

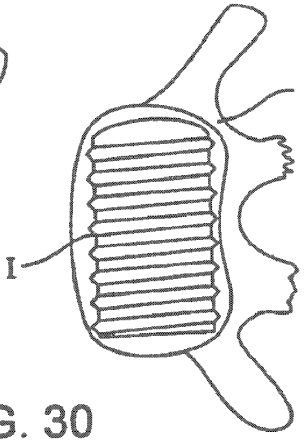


FIG. 30

FIG. 33

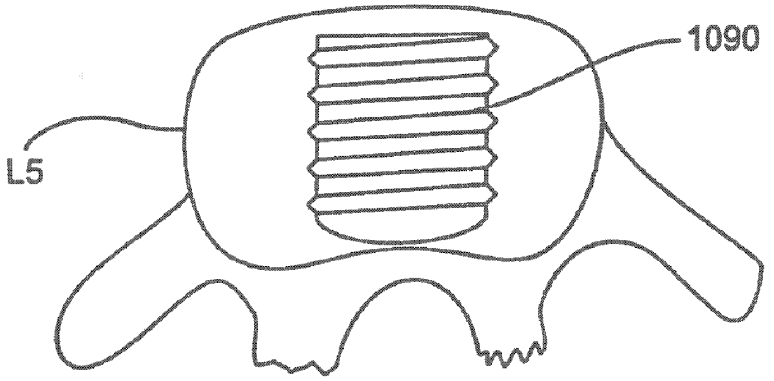
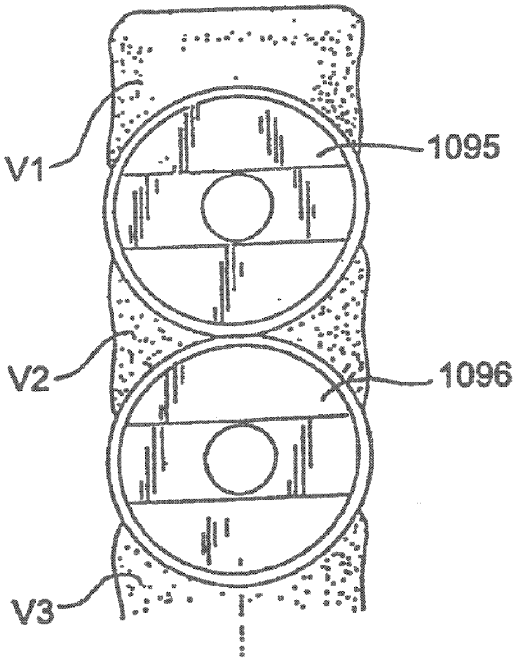


FIG. 34



METHOD FOR INSERTING AN ARTIFICIAL IMPLANT BETWEEN TWO ADJACENT VERTEBRAE ALONG A CORONAL PLANE

This application is a continuation of U.S. application Ser. No. 10/371,757, filed Feb. 21, 2003 (now U.S. Pat. No. 8,066,705); which is a continuation of U.S. application Ser. No. 08/480,461, filed Jun. 7, 1995 (now U.S. Pat. No. 7,491,205); which is a divisional of U.S. application Ser. No. 08/394,836, filed Feb. 27, 1995 (now U.S. Pat. No. 5,772,661); all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to instrumentation and methods of performing surgical procedures on the human thoracic and lumbar spine along the lateral aspect of the spine and from a true lateral or anterolateral approach, and specifically to the surgical correction of thoracic and lumbar disc disease and spinal deformities where concomitant fusion is desired.

2. Description the Prior Art

As regards the thoracic spine, it may be afflicted with a variety of ailments, some so severe as to require surgical intervention. A disc herniation may compress the spinal cord and/or nerve roots and cause pain, loss of function, and even complete paralysis of the legs with loss of bowel and bladder control. The correct treatment for such conditions is the removal of the offending discal tissue. However, this has proven both difficult and quite dangerous. When the discs of the thoracic spine are approached posteriorly (from behind) the spinal cord is in the way. To approach the same herniation anteriorly (from the front) requires the very formidable procedure of thoracotomy (cutting open the chest) and moving the heart and lungs out of the way.

procedures from a lateral approach to the spine (from the side) using fiber optic viewing instruments called thorascopes and numerous small surgical openings through the chest wall (portals) through which various surgical instruments, such as burrs, rongeurs and curettes, may be placed to remove these disc herniations while avoiding formal thoracotomy. Because the discs are very narrow in the thoracic spine and the surgeon is approaching the spine laterally, there is very little space in which to work as the disc is entered in order to get to the back of the disc space. Therefore, the amount of disc removal may be limited. In the alternative, the surgeon might remove the pedicle to gain access to the spinal canal risking further weakening of the already diseased area.

Sometimes, for a variety of reasons including the removal of disc material, the thoracic spine may become unstable (too much motion) at any given level. Historically, this has been treated by fusion, the joining together permanently of the unstable vertebrae via a bridge of bone so as to eliminate all motion at that location. Fusions about the thoracic spine have been performed either anteriorly or posteriorly, either procedure being a rather large surgical undertaking.

Stability of the spine is required for fusion to occur. For this reason, and for the purpose of correcting spinal deformity, it is often necessary to use hardware to rigidly internally fixate (stabilize) the spine. To date, the only benefit the use of the thorascope has provided in this regard is to allow the previous thoracotomy incision to be somewhat smaller.

So to date the following problems remain even utilizing the most recent technology as regards the surgical treatment of thoracic disc disease:

Firstly, the working space within the disc itself to access the herniation which is more posterior is quite limited.

Secondly, multiple or long incisions through the chest are still required.

Thirdly, when fusion is required a major surgical undertaking with its considerable risks is required.

Fourthly, the installation of hardware affixed to the spine still requires a thoracotomy, albeit a smaller one if visualization is assisted via the thorascope.

Fifthly, when, as is often the case, the patient requires all three, that is, discectomy (excision, in part or whole, of an intervertebral disc), fusion, and the application of hardware to the spine, those procedures are performed as serially (one after the other) combined surgical procedures with added surgical times, complications, morbidities, and mortalities.

As regards to the human lumbar spine, the treatment of discal disease with neural compression has generally been from a posterior (from behind) approach. This is sensible as the lumbar discs are generally quite large and it is only those protrusions occurring posteriorly which compress the neural elements which are themselves posterior to the discs. These posterior approaches have included both true posterior approaches and posterolateral approaches to the discs. Further, such approaches have been made via open incisions or through percutaneous stab wounds. In the latter case, instruments are inserted through the stab wounds and monitored by the use of radiographic imaging or the use of an endoscopic viewing device. While it is possible to also decompress a posterior disc herniation in the lumbar spine from an anterior approach (from the front) doing so requires the removal of a very substantial portion or all of the disc material in the front and mid portions of the disc thus leaving that disc incompetent and that spinal segment generally unstable. Therefore, such an anterior approach to the lumbar spine has been reserved for those instances where a fusion is to be performed in conjunction with, and following such a disc removal.

As regards to fusion, the application of bone or bone like substances between bones to induce bony bridging, such procedures have been performed outside the vertebral bodies and/or between the vertebral bodies. The latter being known as an interbody fusion. Such interbody fusions have been performed from posterior, posterolateral and anterior. The adjective applying specifically to the direction from which the bone grafts enter the intervertebral space. Interbody fusion from the posterior approach while still in use has been associated with significant complications generally related to the fact that the delicate dural sac and the spine nerves cover the back of the disc space and are thus clearly in harms way with such an approach. The posterolateral approach has generally been utilized as a compliment to percutaneous discectomy and has consisted of pushing tiny fragments of morsalized bone down through a tube and into the disc space.

Anterior interbody spinal fusion is performed from a straight anterior position as regards the path of entry of the fusion material into the intervertebral space. Such an anterior position is achieved in one of two ways. First, by a straight anterior approach which requires that the peritoneal cavity, which contains the intestines and other organs, be punctured twice, once through the front and once through the back on the way to the front of the spine; or secondly, by starting on the front of the abdomen off to one side and dissecting behind the peritoneal cavity on the way to the front of the spine. Regardless of which approach to the front of the spine is used, and apart from the obvious dangers related to the dense anatomy and vital structures in that area, there are at least two major problems specific to the anterior interbody fusion angle of implant insertion itself. First, generally at the L_4 L_5 disc, the

great iliac vessels bifurcate from the inferior vena cava lie in close apposition to, and, covering that disc space making fusion from the front both difficult and dangerous. Secondly, anterior fusions have generally been done by filling the disc space with bone or by drilling across the disc space and then filling those holes with cylindrical implants. As presently practiced, the preferred method of filling the disc space consists of placing a ring of allograft (bone not from the patient) femur into that disc space. An attempt to get good fill of the disc space places the sympathetic nerves along the sides of the disc at great risk. Alternatively, when the dowel technique is used, because of the short path from the front of the vertebrae to the back and because of the height of the disc as compared to the width of the spine, only a portion of the cylindrical implant or implants actually engages the vertebrae, thus, compromising the support provided to the vertebrae and the area of contact provided for the fusion to occur.

There is therefore, in regard to the lumbar spine, a need for a new method and means for achieving interbody fusion which method avoids the problems associated with all prior methods, and which have included, but are not limited to, nerve damage when performed posteriorly, or the need to mobilize the great vessels when performed anteriorly. Further, the size of the implants are limited by the dural sac posteriorly, and the width of the spine and the delicate vital structures therewith associated anteriorly. An improved method and means for interbody fusion should provide for optimal fill of the interspace without endangering the associated structures and allow for the optimal area of contact between the implant or implants and the vertebrae to be fused.

SUMMARY OF THE INVENTION

The present invention is directed to methods and instrumentation for performing surgery on the spine along its lateral aspect (side) and generally by a lateral or an anterolateral surgical approach, such that the instruments enter the body from an approach that is other than posterior and make contact with the spine along its lateral aspect. The present invention provides for the entire surgical procedure to be performed through a relatively small incision and may be performed in either the thoracic or lumbar spine.

In the preferred embodiment, the instrumentation of the present invention comprises a guide pin, a distractor, an extended outer sleeve, an inner sleeve and drill adjustable for depth and with a depth limiting means. The distractor of the present invention is used for initially distracting (spacing apart) and realigning adjacent vertebrae of the spine and also functions as an alignment rod for inserting the extended outer sleeve. The distractor is placed at the affected disc space between adjacent vertebrae through a small incision in the body. For example, for surgery in the thoracic spine, a small incision in the chest cavity of the patient is made from a lateral approach to the thoracic spine. For surgery in the lumbar spine a small incision may be made in the abdominal wall of the patient. The insertion of the distractor may be guided by a guide pin previously inserted in the disc space and visually monitored for proper orientation and placement by the surgeon either indirectly through an image intensifier, or directly through a thorascope or by direct vision.

The extended outer sleeve in the preferred embodiment is a hollow tubular member having an extension member that is inserted in the disc space and is capable of distracting and aligning the two adjacent vertebrae from the lateral aspect of the spine. In the preferred embodiment, the extended outer sleeve has a pair of prongs for fixedly engaging the two adjacent vertebrae and further stabilizing the adjacent vertebrae. With the distractor in place in the affected disc space, the extended outer sleeve is placed over the distractor, and the distractor guides and aligns the insertion of the extended outer sleeve. As the extended outer sleeve is seated, the extension member becomes inserted in the disc space and the prongs engage the outside wall of the adjacent vertebrae. The distractor is then removed and the extended outer sleeve maintains the proper distraction and alignment of the adjacent vertebrae. The remainder of the surgical procedure consisting of disc removal, fusion, and rigid internal stabilization may all be performed via the dosed space within the extended outer sleeve. Alternatively, a convertible extended outer sleeve comprising a hollow tubular member that can be dissociated from its insertion end which remains engaged to the vertebrae to maintain distraction and alignment, may be used where it is desired to have direct visualization and access to the surgical site for at least a portion of the surgical procedure.

The drilling out and the subsequent removal of a rather significant mass of the disc itself may be curative in relieving a posterior disc herniation as the mass of tissue pushing from within the disc outward and posteriorly is thus removed. Further, the distractor in driving the vertebrae apart exerts significant tension on the walls of the disc which are pulled straight also tending to correct any disc herniation. Finally, since the hole drilled across the disc space is quite close to the posterior borders of the vertebrae, it makes the removal of any persisting posterior disc herniation quite simple. With the drill removed and the extended outer sleeve cleaned out by irrigation and suction, one can then place the endoscope directly down the outer sleeve and into the large space created by the removal of the disc, and in the preferred method, the adjacent vertebral bone, and then remove any remaining fragments of disc using conventional hand held instruments such as rongeurs and curettes under endoscopic visualization.

When it is desirable to remove posterior disc material, then a specialized modification of the extended outer sleeve having at its distal end a spine engaging portion comprising one anterior extension and posteriorly two prongs one each above and below the disc space may be used. Further, such an extended outer sleeve may be configured such that the great length of the hollow tubular portion of the extended outer sleeve is detachable, as by unscrewing, from the distal working end such that when uncoupled the distal end may remain in place maintaining distraction even after the hole is drilled and thus allowing the surgeon to work through that remaining portion of the extended outer sleeve and the space provided by the drilling to remove the posterior disc material under direct vision. For those instances where the surgeon has elected to access the spine through a more standard incision and is viewing the spine directly, the surgeon is then able to continue to operate through the distal spine engaging portion of the extended outer sleeve and still maintain the distraction and alignment of the vertebrae.

A spinal implant may then be inserted through the extended outer sleeve and into the hole in the adjacent vertebrae. The extended outer sleeve is removed once the spinal implant has been inserted. If the spinal implant being inserted has surface projections such as a thread, then an inner sleeve is inserted in the extended outer sleeve prior to drilling to accommodate the height of the projections or as in the case of a thread, the difference between the major and minor diameters of the implant.

To further stabilize the spinal implant, a staple alignment rod may be mechanically coupled to the spinal implant prior to the removal of the extended outer sleeve. The extended outer sleeve is then removed and a staple having spine engaging prongs is inserted via the alignment rod and is coupled to

the spinal implant. The alignment rod is removed and replaced with a locking screw to secure the staple to the spinal implant.

While the preferred method utilizing a cylindrical implant and involving the removal of some bone from each of the adjacent vertebrae in preparation for fusion has been described, it is understood that the distractor and sleeve could as well be rectangular and the drill supplemented with or replaced by a box chisel, or other chisel so as to produce a rectangular fusion site or similarly any of a variety of shapes. Further, it is understood that the outer sleeve could be dimensioned so as to confine the removal of the disc material, regardless of the means, to the area between the adjacent vertebrae rather than providing for the removal of the bone as well.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide instrumentation for performing surgery on the thoracic spine through the chest cavity from a lateral approach to the spine.

It is another object of the present invention to provide a method of performing surgery on the thoracic spine through the chest cavity from a lateral approach to the spine that is safer, more effective and faster than previously possible.

It is a further object of the present invention to provide instrumentation and method of inserting a spinal implant in a hole drilled across the disc space and into two adjacent vertebrae of the thoracic spine through the chest cavity from a lateral approach to the spine.

It is another object of the present invention to provide for a method and instrumentation for performing a thoracic discectomy, an interbody fusion, and rigid internal fixation of the spine through the chest cavity from a lateral approach and all as a single integrated procedure.

It is yet another object of the present invention to provide for a method and instrumentation for performing a lumbar fusion from the lateral aspect of the spine.

it is further another object of the present invention to provide for a method and instrumentation for performing a lumbar fusion and spinal canal decompression from the lateral aspect of the spine.

It is further still another object of the present invention to provide for a method and instrumentation for performing a lumbar fusion, decompressive discectomy, and a rigid internal fixation of the spine and all as a single integrated surgical procedure.

It is further yet another object of the present invention to provide for a method and instrumentation to achieve discectomy, fusion and interbody stabilization of the lumbar without the need to mobilize the great vessels from the front of the vertebral bodies.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a rear perspective view of a segment of the thoracic spine with the guide pin of the present invention about to be inserted from a lateral approach to the thoracic spine into the disc space between two adjacent vertebrae.

FIG. **2** is a rear perspective view of a segment of the thoracic spine with the guide pin inserted in the disc space between two adjacent vertebrae and the distractor of the present invention about to be placed over the guide pin.

FIG. **3** is an enlarged front elevational view of a segment of the thoracic spine along line **3** of FIG. **2** having a portion of the top vertebrae removed and a portion of the disc removed with the guide pin, shown partially in hidden line, inserted from a lateral approach to the thoracic spine into the disc space.

FIG. **4** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the guide pin and distractor, shown partially in hidden line, inserted from a lateral approach to the thoracic spine in the disc space.

FIG. **5** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the distractor, shown partially in hidden line, inserted from a lateral approach to the thoracic spine and seated in the disc space and the guide pin removed.

FIG. **6** is a rear perspective view of a segment of the thoracic spine having a distractor inserted from a lateral approach to the thoracic spine and seated in the disc space and the extended outer sleeve of the present invention coupled to a driver cap and about to be placed over the distractor.

FIG. **7** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the distractor and the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space.

FIG. **7**A is side perspective view of the extended outer sleeve of the present invention.

FIG. **8** is a rear perspective view of a portion of the thoracic spine with the extended outer sleeve fully seated over the distractor inserted from a lateral approach to the thoracic spine and seated in the disc space and with the driver cap removed.

FIG. **9** is a front elevational view of a segment of the thoracic spine of FIG. **3** with the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the adjacent vertebrae showing the distractor being removed by a distractor puller.

FIG. **10** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae.

FIG. **11** is a front elevational view of a segment of the thoracic spine of FIG. **3** with the inner sleeve of the present invention being inserted into the extended outer sleeve.

FIG. **12** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the inner sleeve, shown in partial hidden line, inserted into the extended outer sleeve that is inserted from a lateral approach to the thoracic spine in the disc space and engages two adjacent vertebrae.

FIG. **13** is a side elevational view of a segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine in the disc space and engaging the two adjacent vertebrae with the inner sleeve and drill shown in an exploded view and partially in hidden line.

FIG. **14** is a cross sectional view along lines **14-14** of FIG. **13** of the drill, inner sleeve and extended outer sleeve.

FIG. **15** is a cross sectional view along lines **15-15** of FIG. **13** of the collar for limiting the drilling depth of the drill.

FIG. **16** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae, the inner sleeve inserted in the extended outer sleeve, and the drill passing through the inner sleeve to create a hole across the disc space and into the adjacent vertebrae.

FIG. **17** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae illustrating a hole drilled across the disc space and into the adjacent vertebrae.

FIG. **18** is a front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae, an implant driver, and a spinal implant about to be inserted through the extended outer sleeve and into the hole drilled across the disc space and into the adjacent vertebrae.

FIG. **19** is a front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae and a spinal implant implanted in the hole drilled across the disc space and into two adjacent vertebrae.

FIG. **20** is a front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae and an extractor cap for removing the extended outer sleeve about to be coupled to the extended outer sleeve.

FIG. **21** is an enlarged partial sectional view of the extractor cap engaging the extended outer sleeve.

FIG. **22** is a front elevational view of the segment of the thoracic spine of FIG. **20** with the distractor puller coupled to the extractor cap shown removing the outer sleeve from the disc space and the adjacent vertebrae in the direction of the arrow.

FIG. **23** is an enlarged front elevational view of a segment of the thoracic spine having a portion of the top vertebrae removed and a portion of the disc space removed and a spinal implant implanted from a lateral approach to the thoracic spine in the hole drilled across the disc space and into the two adjacent vertebrae.

FIG. **24** is a front elevational view of a segment of the thoracic spine having a spinal implant implanted from a lateral approach to the thoracic spine into a hole drilled across the disc space and into the adjacent vertebrae with a spinal fixation device coupled to the spinal fusion implant and engaging the adjacent vertebrae to lock the spinal implant in place.

FIG. **25** is a side perspective view of an alternative embodiment of the extended outer sleeve of the present invention having a pair of extension members and a pair of prongs.

FIG. **26** is a top plan view of the extended outer sleeve of FIG. **25** shown in partial cutaway with an inner sleeve and a drill inserted within its interior and placed adjacent to a vertebra of the spine with the major vessels and the dural sac and spinal nerves proximate to the vertebra shown in cross section.

FIG. **27** is an anterior elevational view of a vertebra of the spine with the extended outer sleeve of FIG. **26** shown inserted from the lateral approach and seated in the disc space and engaging the vertebra.

FIG. **28** is a posterior elevational view of a vertebra of the spine with the extended outer sleeve of FIG. **25** shown inserted from the lateral approach of the spine and seated in the disc space and engaging the vertebra.

FIG. **29** is a side elevational view of a segment of the lumbar spine with a first spinal implant inserted from the lateral aspect into a hole drilled across a first disc space and into two adjacent vertebrae, and a second spinal implant inserted from the lateral aspect into a second hole drilled across a second disc space and into two adjacent vertebrae.

FIG. **30** is top sectional view along lines **30-30** of FIG. **29** showing the area of contact of the first spinal implant and the vertebra.

FIG. **30**A is a top sectional view similar to FIG. **30** showing the area of contact of a spinal implant inserted from slightly anterior (anterolateral) along the lateral aspect of the spine and oriented at least partially from side to side with respect to the vertebra.

FIG. **31** is an anterior elevational view of a segment of the lumbar spine with spinal cylindrical implants inserted from the anterior of the spine into holes drilled across the same disc space and into two adjacent vertebrae.

FIG. **32** is a top sectional view along lines **31-31** of FIG. **31** showing the area of contact of the two spinal implants and the vertebra which is the same size as the vertebra of FIG. **30**.

FIG. **33** is a top sectional view of a single implant having a diameter equal to the diameter of the implant of FIG. **30** showing the area of contact with the vertebra which is the same size as the vertebra of FIG. **30**.

FIG. **34** is a side elevational view of a segment of the spinal column with two spinal implants inserted from front to back at adjacent disc levels between three vertebrae.

FIG. **35** is a perspective side view of an alternative embodiment of the extended outer sleeve of the present invention having a removable distal end with a single extension member and a pair of prongs.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. **1**, a rear perspective view of a segment of the thoracic spine S is shown with a guide pin **30** about to be inserted from a lateral approach (through the lateral chest wall) to the thoracic spine S into the disc space D between two adjacent vertebrae, for example vertebrae T_7 and T_8. The guide pin **30** may first be used as radiological marker to confirm the correct disk level and instrument position, and then functions to align and guide the insertion of the instrumentation described below into the disc space D. The guide pin **30** is inserted through a small incision on the side of a patient's chest cavity perpendicular to the lateral aspect of the vertebrae T_7 and T_8 of the thoracic spine S. The guide pin **30** is made of a material appropriate for surgical use and comprises a shaft portion **40**, a tip **50** which may be pointed to facilitate insertion into the disc space D, and a distal end **60**. In the preferred embodiment, the guide pin has a diameter in the range of 1.5 mm to 5.0 mm, with 2.5 mm being the preferred diameter, and a length in the range of 200 mm to 800 mm, with 350 mm being the preferred length.

Referring to FIGS. **2** and **3**, the guide pin **30** is shown inserted from a lateral approach to the thoracic spine S and into the disc space D between adjacent vertebrae T_7 and T_8, with a substantial part of the shaft portion **40** of the guide pin **30** remaining external to the disc space D and functions as a guide post. The tip **50** of the guide pin **30** may penetrate the disc space D for a substantial part of the transverse width W of the vertebrae T_7 and T_8 such that at least a part of the shaft portion **40** is within the disc space D. The guide pin **30** is firmly embedded in the discal material present within the disc space D, but does not protrude through the opposite side of the disc space D to prevent any unwanted damage to that area. The guide pin **30** is placed in the disc space D so that it is parallel to the end plates of the vertebrae T_7 and T_8, and centered within the disc space D to bisect the disc space D along the transverse width W of the vertebrae T_7 and T_8. In

this manner, a substantial portion of the vertebrae T_7 and T_8 is present near the circumference of the guide pin **30** such that instruments having a diameter greater than the guide pin **30** may be inserted into the vertebrae T_7 and T_8 coaxial to the guide pin **30** without protruding from the vertebrae T_7 and T_8. Such instruments are guided and aligned during insertion by the guide pin **30** so that they are correctly oriented with respect to the vertebrae T_7 and T_8. The surgeon may monitor the correct orientation of the guide pin **30** within the disc space D indirectly with an image intensifier, or directly with a thorascope if one is being used.

Once inserted in the disc space D, the guide pin **30** functions as a guide post for a distractor **100** which is placed over the guide pin **30** and inserted in the disc space to distract the disc space D and align the adjacent vertebrae T_7 and T_8 by urging them apart. Circumstances permitting, the surgeon may elect to bypass the use of the guide pin **30** and insert the distractor **100** directly. The distractor **100** has a cylindrical barrel **106** that terminates at one end in a reduced diameter disc penetrating portion **102** that is essentially cylindrical, with a further reduced diameter, bullet-shaped front end **103** to facilitate insertion into the disc space D. The distractor **100** has a shoulder portion **104** where the penetrating portion **102** extends from barrel **106** and has a hallow longitudinal passageway **107** extending the entire length of the distractor **100** for receiving the guide pin **30**. The passageway **107** of the distractor **100** is open at both ends of the distractor **100** and has a diameter that is slightly greater than the diameter of the shaft portion **40** of guide pin **30**. The shaft portion **40** of the guide pin **30** may pass through the passageway **107** as the distractor **100** is placed coaxially over the guide pin **30**. In this manner, the distractor **100** can be guided and aligned by the guide pin **30** so that it is inserted into the disc space D coaxial to the guide pin **30** and is properly aligned with respect to the vertebrae T_7 and T_8. Once the distractor **100** is properly placed within the disc space D, the guide pin **30** may be removed from the disc space D through the passageway **107** of the distractor **100**.

The appropriate placement of distractor **100** in the disc space D may be determined visually by the surgeon by the use of a thorascope and or by the use of radiographic, fluoroscopic, or similar procedures, such as utilizing an image intensifier, all of which allow the surgeon to determine the correct orientation and placement of the guide pin **30** and distractor **100** within the disc space D. The correct orientation and placement of the distractor **100** is important to the success of the method of the present invention, as the purpose of the distractor **100** is to space part and align the vertebrae T_7 and T_8 and to guide the insertion into the disc space D of the extended outer sleeve **140** described in detail below. As the diameter of the distracter **100** is almost the same as the inner diameter of the extended outer sleeve **140** and is the same as the spinal implant I, also described in detail below, the surgeon can use x-rays to determine whether the distractor **100** is properly oriented with respect to the adjacent vertebrae T_7 and T_8, such that any subsequent drilling through the extended outer sleeve **140** and insertion of spinal implant I will be correctly oriented with respect to the vertebrae T_7 and T_8. Such a precaution will permit the surgeon to correct any misplacement of the distractor **100** before any irreversible drilling or implant insertion has occurred.

The penetrating portion **102** of the distractor **100** may be of various diameters and lengths, the preferred length being less than the known transverse width W (side to side) of the vertebrae T_7 and T_8. This combined with the circumferential shoulder portion **104** of the distractor **100**, which is too large to fit within the disc space D, protects against the danger of overpenetration. The barrel **106** of the distractor **100** may have at its distal end a recessed portion **108** below the crown **110** which allows for the distractor **100** to be engaged by an extractor unit shown in FIG. **9**.

In the preferred embodiment of the distractor **100**, the barrel **106** has a diameter in the range of 10 mm to 30 mm, with 20 mm being the preferred diameter, and the penetrating portion **102** has a diameter in the range of 3 mm to 10 mm, with 6 mm being the preferred diameter.

Referring to FIGS. **4** and **5**, once the distractor **100** is inserted into the disc space D, the penetrating portion **102** of the distractor **100** distracts the vertebrae T_7 and T_8 apart, such that the vertebrae T_7 and T_8 to either side of the penetrating portion **102** are forced into full congruence and thus become parallel, not only to the penetrating portion **102**, but to each other. Because of the forced opposition of the vertebrae T_7 and T_8 to the penetrating portion **102** the distractor **100** will then come to lie absolutely perpendicular to the plane P of the lateral aspect of the thoracic spine S and absolutely parallel to the vertebral endplates, allowing optimal alignment for the procedure to be performed.

Referring to FIGS. **6**, **7** and **7**A, the distractor **100** now serves as both a centering post and an alignment rod for the extended outer sleeve **140** which is fitted over the distractor **100** and inserted into the disc space D. As shown in FIG. **7**A, the extended outer sleeve **140** is a hollow tubular member made of material appropriate for surgical use and preferably metal, and has an inner diameter sufficiently sized to receive the distractor **100**. The inner diameter of the extended outer sleeve **140** closely matches the outer diameter of the distractor **100**, so that a dose fit is achieved and the extended outer sleeve **140** is precisely guided by the distractor **100**. The extended outer sleeve **140** has at its distal end **146** an extension member **148** and two prongs **149** and **150** sufficiently spaced apart to penetrate and hold fixed the two adjacent vertebrae T_7 and T_8. The extension member **148** is essentially a continuation of the extended outer sleeve **140** and the prongs **149** and **150** are offset from the extended outer sleeve **140** or can also be a continuation of the extended outer sleeve **140** like extension member **148**. The prongs **149** and **150** may have sharp insertion edges **152** and **154** to facilitate insertion into the vertebrae T_7 and T_8.

Where the surgery is for a disc herniation, the extension member **148** of the extended outer sleeve **140** located anteriorly is used without a second extension member posteriorly, as the use of the two prongs **149** and **150** in conjunction with the anterior extension member **148** makes it possible to operate through the extended outer sleeve **140** posteriorly, without obstruction and with good visibility when an endoscope is used such that any remaining disc herniation may be removed. The extension member **148** of the extended outer sleeve **140** provides a protective barrier to the structures lying beyond it.

However, if the surgery is not for a disc herniation, but for example, for stabilization of the spine, then the extended outer sleeve may have both an anterior extension member **148** and a corresponding posterior extension member with or without prongs, such as the extended outer sleeve **1100** shown in FIG. **35** and described in greater detail below.

In the preferred embodiment, the extension member **148** of the extended outer sleeve **140** functions to maintain the distraction and alignment of the vertebrae T_7 and T_8, as the extension member **148** is being inserted from the lateral aspect of the thoracic spine S. Without the extension member **148**, in order to maintain the proper distraction of the adjacent vertebrae T_7 and T_8, it would be necessary to place a surgical instrument, such as a second distractor (not shown) on the

opposite side of the vertebrae T_7 and T_8. This would require a second incision in the opposite side of the patient's chest cavity for insertion of the required surgical instruments. Further, as it is desired to insert an implant of the maximum possible length across the transverse width W of the vertebrae T_7 and T_8, the presence of any instrumentation at the opposite end of the vertebrae T_7 and T_8, would interfere with the insertion of such an implant. For example, the second distractor on the opposite side of the vertebrae T_7 and T_8 would be in the way of a drill used to create a hole across the transverse width W of the vertebrae T_7 and T_8, since the drilled opening would overlap the second distractor. Therefore, the extension member **148** solves the problem of maintaining an even distraction of the two adjacent vertebrae T_7 and T_8 across their transverse width W from only one side of the thoracic spine S, allowing for the unimpeded insertion of instruments and/or implants. While in the preferred embodiment, the extended outer sleeve **140** has an extension member **148**, it is also possible to have an extended outer sleeve without any extension members and instead, having prongs of sufficient length that engage the bone of the adjacent vertebrae to maintain the distraction and alignment of the adjacent vertebrae created by the distractor **100**. However, the use of such an extended outer sleeve capable of holding, but not of obtaining, the desired intervertebral distraction and alignment would require the use of a distractor prior to its insertion as earlier described herein.

In the preferred embodiment of the extended outer sleeve **140**, a single extension member **148** is present and oriented anteriorly to protect the major vessels located to the anterior aspect of the thoracic spine S. The extended outer sleeve **140** has no extension member near the posterior aspect the spine as it is often necessary to access the spinal canal in order to remove any diseased discal material. In the special circumstances where only vertebral fusion is desired, the extended outer sleeve **140** may have a second extension member (not shown) identical to the extension member **148** positioned diametrically opposite the extension member **148** in order to protect the spinal canal, and in such instance may or may not have the bone penetrating prongs **149** and **150**.

The extension member **148** of the extended outer sleeve **140** has a height that is generally approximately equal to the diameter of the penetrating portion **102** of the distractor **100**, such that the extension member **148** is capable of maintaining the spacing created by the insertion of the distractor **100** between the adjacent vertebrae T_7 and T_8 which is generally the restoration to normal of the disc space D. The extension member **148** is tapered at its leading edge **151** to facilitate insertion into the disc space D and is positioned approximately 120 degrees from each of the two prongs **149** and **150**. The extension member **148** of the extended outer sleeve **140** works in conjunction with the prongs **149** and **150** which engage the vertebrae T_7 and T_8, respectively, to maintain the distraction and alignment of the vertebrae T_7 and T_8. Further, the prongs **149** and **150** not only hold the vertebrae T_7 and T_8 apart, but during drilling also help to hold them together so as to resist them moving apart.

In the preferred embodiment, the extension member **148** of the extended outer sleeve **140** has a length that is less than the transverse width W of the vertebrae T_7 and T_8. The extension member **148** needs to be relatively long because it must maintain distraction of the adjacent vertebrae T_7 and T_8 when placed across the transverse width W of the vertebrae T_7 and T_8. Therefore, if the extension member **148** is shorter than one half the transverse width W of the vertebrae T_7 and T_8, it may not be capable, of distracting and aligning the vertebrae T_7 and T_8, and a second distractor would be required as described above, to achieve the correct distraction and alignment of the vertebrae T_7 and T_8.

In the preferred embodiment, the extended outer sleeve **140** has an outer diameter in the range of 12 mm to 34 mm, with 24 mm being the preferred outer diameter, and an inner diameter in the range of 10 mm to 28 mm, with 20 mm being the preferred inner diameter of the extended sleeve **140**.

In the preferred embodiment, the extension member **148** of the extended outer sleeve **140** has a length in the range of 14 mm to 30 mm, with 24 mm being the preferred length, and a height in the range of 3 mm to 10 mm, with 6 mm being the preferred height. In the preferred embodiment, the prongs **149** and **150** of the extension member **140** have a length in the range of 6 mm to 20 mm, with 14 mm being the preferred length and a diameter in the range of 2 mm to 3 mm, with 2 mm being the preferred diameter of the prongs **149** and **150**.

Referring specifically to FIG. **6**, coupled to the proximal end **157** of the extended outer sleeve **140** is a driver cap **160** in the form of an impaction cap which has at its far end a flat, closed-back surface **162** and at its other end a broad, circular opening. The driver cap **160** is used for driving the extended outer sleeve **140** toward the vertebrae T_7 and T_8 and fits over both the extended outer sleeve **140** and the distractor **100**. An impaction force, such as a mallet blow, is applied to surface **162** of the driver cap **160** to advance the extended outer sleeve **140**. That force is transmitted to the extended outer sleeve **140** via its proximal end **157**, seating the prongs **149** and **150** of the extended outer sleeve **140** into the vertebrae T_7 and T_6 and inserting the extension member **148** into the disc space D. As the extended outer sleeve **140** is advanced forward, the crown **110** of the distractor **100** is allowed to protrude within the driver cap **160** unobstructed until it contacts the interior of the driver cap **160**, such that further taps of the mallet will not further advance the extended outer sleeve **140**. Any further motion is resisted by the flat shoulder portion **104** of the distractor **100** abutting the hard lateral outer surfaces of the adjacent vertebrae T_7 and T_8. The flat, planar area **156** of the distal end **146** of extended outer sleeve **140** serves to resist the further insertion of the extension member **148** into the disc space D and to resist further insertion of the prongs **149** and **150** into the vertebrae T_7 and T_8. In this way, the extended outer sleeve **140** is safely and assuredly inserted to its optimal depth, and no further, and rigidly secures the two adjacent vertebrae T_7 and T_8 as shown in FIG. **7**.

Referring to FIGS. **8** and **9**, the driver cap **160** is then removed and the crown **110** and the recessed portion **108** of the distractor **100** protrude from the proximal end **157** of the extended outer sleeve **140**. The distractor **100** may now be removed from within the extended outer sleeve **140** since the extended outer sleeve **140** functions to maintain the distraction and alignment of the vertebrae T_7 and T_8. The extended outer sleeve **140** is held secure by the extension member **148** inserted within the disc space D and by the prongs **149** and **150** engaging the vertebrae T_7 and T_8.

A distractor puller **200** is utilized to remove the distractor **100** in the direction of arrow Y from within the disc space D leaving the extended outer sleeve **140** in place. The distractor puller **200** has front portion **202**, a mid portion **204**, and a back handle portion **206**. The front portion **202** of the distractor puller **200**, is connected to one end of shaft **210** which at its far end is connected to the back handle portion **206**. The distractor puller **200** is described in detail in copending U.S. application Ser. No. 08/074,781, entitled APPARATUS AND METHOD FOR INSERTING SPINAL IMPLANT, and is incorporated herein by reference. The socket-like front portion **202** of the distractor puller **200** engages the circumferential recessed portion **108** of the distractor **100**.

A cylindrical and freely movable weight **216** is fitted around shaft **210** between the front portion **202** and the rear handle portion **206** of the distractor puller **200** so as to form a slap hammer. The weight **216** of the distractor puller **200** is gently and repeatedly slid along the shaft **210** and driven rearwardly against flat surface **228** of the rear handle portion **206** to transmit a rearward vector force to front portion **202** and to the distractor **100** to which it is engaged. In this manner, the distractor **100** is removed from within the disc space D and out of the extended outer sleeve **140** without disturbing it.

Referring to FIG. **10**, once the distractor **100** has been completely removed from within the extended outer sleeve **140** and from within the disc space D, the extension member **148** remains within the disc space D and the prongs **149** and **150** rigidly maintain the appropriate distraction and the relative position of the adjacent vertebrae T_7 and T_8. The remainder of the procedure occurs entirely through the extended outer sleeve **140** and the space therein is sealed off from any of the organs of the chest.

Referring to FIGS. **11** and **12**, since the extended outer sleeve **140** is of a fixed length and rigid, the flat rearward surface **172** of the distal end **146** may be used as a stop to the advancement of any instruments placed through the extended outer sleeve **140**, thus protecting against accidental overpenetration. Further, the extended outer sleeve **140** assures that the further procedure to be performed will occur coaxial to the disc space D and further, be symmetrical in regard to each of the adjacent vertebrae T_7 and T_8.

Where it is desirable to drill a hole smaller in diameter than the spinal implant to be inserted, such as in the case where the spinal implant is threaded, an inner sleeve **242** which functions as a drill guide and spacer having a thickness which corresponds to the difference between the major and minor diameters of the spinal implant, is inserted in the proximal end **158** of the extended outer sleeve **140**. The inner sleeve **242** is a hollow tubular member comprising a barrel portion **243** and a cuff portion **244** having a greater outer diameter than the barrel portion **243**. The cuff portion **244** of the inner sleeve **242** seats against the flat rearward surface **172** of the extended outer sleeve **140** to prevent further insertion of the inner sleeve **242**. The distal end **246** of the inner sleeve **242** extends towards but does not impact the lateral aspect of the adjacent vertebrae T_7 and T_8 in the interior of the extended outer sleeve **140** when fully seated. The barrel portion **243** of the inner sleeve **242** has an outer diameter that fits within the inner diameter of the extended outer sleeve **140**. In the preferred embodiment, the barrel portion **243** of the inner sleeve **242** has an outside diameter in the range of 10 mm to 28 mm, with 20 mm being the preferred outer diameter, and a wall thickness in the range of 0.5 mm to 3 mm, with approximately 0.75 to 1.5 mm being the preferred thickness.

Referring to FIGS. **13-15**, once the inner sleeve **242** is seated within the extended outer sleeve **140**, a drill **250** connected to a handle **260** or to a drill motor (not shown), is introduced through the aperture in the proximal end **248** of the inner sleeve **242** and utilized to create a hole across the disc space D and into the adjacent vertebrae T_7 and T_8. The drill **250** reams out arcs of bone which it engages from the adjacent vertebrae T_7 and T_8, as well as any discal material within its path down to its predetermined and limited depth. It is appreciated that if an inner sleeve **242** is not used, the drill **250** may be placed directly into the extended outer sleeve **140** to create a hole across the disc space D and into the adjacent vertebrae T_7 and T_8.

The drill shaft of drill **250** comprises an upper portion **252**, a central recessed portion **254** of a smaller diameter and a lower cutting portion **256**. The drill **250** has a narrow engagement portion **258**, which allows it to be affixed to a driving mechanism which may be either a manual unit such as, handle **260**, or a power unit such as an electric drill motor. The upper portion **252** has a plurality of grooves **261** for engaging a circumferential collar **262** of an increased diameter which serves to limit the depth of penetration of the drill **250** and may be fixed, or lockably adjustable.

Referring to FIG. **15**, a cross sectional view of the circumferential collar **262** is shown engaging the upper portion **252** of the shaft of drill **250**. The collar **262** comprises diametrically opposite first and second flanges **264** and **266**. The first and second flanges **264** and **266** are pivotably attached to the collar **262** by first and second pins **268** and **270** and spring biased by first and second spring **272** and **274**. The first and second flanges **264** and **266** of the collar **262** are contoured to correspond to the curvature of the upper portion **252** of the drill **250**. The first and second flanges **264** and **266** engage one of the grooves **261** when in the full biased position as shown in FIG. **15**. To disengage the grooves **261**, the first and second **264** and **266** are compressed together by the surgeon such that the first and second springs **272** and **274** are compressed and the first and second flanges **264** and **266** pivot away from the upper portion **252** of the shaft, such that the collar **262** can slide along the upper portion **252** of the drill **250**. The first and second flanges **264** and **266** of the collar **262** are oriented opposite each other and need to be compressed together in order to disengage the grooves **261**. The compression of one of the flanges **264** and **266** alone will not disengage the collar **262** from the grooves **261**. In this manner, collar **262** can not become accidentally disengaged during the rotation of the drill **250**.

While it is believed that this mechanism is entirely novel, it is appreciated that various mechanisms to lockably adjust drills are well-known to those skilled in the art. Such mechanisms include, but are not limited to, the use of collets, threaded shafts with lock nuts, and flanges engaging grooves forced therein by either a cap pulled over the flanges or screwed down upon them.

Referring to FIGS. **13** and **14**, in the preferred embodiment, the forward cutting edge **280** of drill **250** is a four cutting edge end mill modification of a large fluted drill design. The cutting portion **256** of the drill **250** resembles an end cutting mill which may contain any workable number of cutting surfaces, but preferably four or more, that are relatively shallow such that the advancement of the drill **250** occurs more slowly. The cutting portion **256** of the drill **250** may be of a different diameter depending on the type of spinal implant that is being inserted. If the spinal implant being inserted is threaded, the outside diameter of the cutting portion **256** of the drill **250** would generally correspond to the minor diameter of the threaded implant. The inner sleeve **242** has an inner diameter slightly greater than the minor diameter of a threaded implant and its outer diameter is slightly smaller than the inside diameter of the extended outer sleeve **140** which has the same outer diameter as the major diameter (with threads) of the threaded implant. If the implant is not threaded, the outside diameter of the drill **250** corresponds to the inside diameter of the extended outer sleeve **140** such that a hole the maximum diameter of the extended outer sleeve may be drilled.

The inner sleeve **242** serves many functions. First, it provides an intimate drill guide for drill **250** in the event a smaller diameter hole is to be drilled than that of the inside diameter of the extended outer sleeve **140**. Second, since the inner sleeve **242** guides the drill **250**, it allows for the extended outer sleeve **140** to have an internal diameter large enough to

admit a threaded implant, which is larger in diameter than the outer diameter of the drill **240**.

If a larger extended outer sleeve **140** were utilized absent the inner sleeve **242**, then the drill **250** would be free to wander within the confines of that greater space and would not reliably make parallel cuts removing equal portions of bone from the adjacent vertebrae T_7 and T_8. Further, the bone removal not only needs to be equal, but must be correctly oriented in three dimensions. That is, the path of the drill **250** must be equally centered within the disc space, parallel the endplates, and perpendicular to the long axis of the spine dissecting the disc space D.

A further purpose of the inner sleeve **242** is that it may be removed simultaneously with the drill **250**, thereby trapping the debris, both cartilaginous and bony, generated during the drilling procedure. The debris is guided rearward by the large flutes **251** of the lower cutting portion **256** and is collected around the central recessed portion **254** and then contained and between the recessed portion **254** and the inner wall of the inner sleeve **242**. Thus, by removing the drill **250** in conjunction with the inner sleeve **242**, much of the debris generated by the drilling procedure is safely removed from the drilling site.

Referring to FIG. **17**, once the drill **250** and the inner sleeve **242** are removed from the extended outer sleeve **140** a cylindrical hole **290** remains across the disc space D and into the two adjacent vertebrae T_7 and T_8. The cylindrical hole **290** is oriented across the transverse width W of the vertebrae T_7 and T_8, in which an implant of appropriate diameter is to be implanted. The proper distraction and orientation of the two adjacent vertebrae T_7 and T_8 is maintained by the extension member **148** and the prongs **149** and **150** of the extended outer sleeve **140**.

The cylindrical hole **290** may then be irrigated and vacuumed through the extended outer sleeve **140** to remove any remaining debris from the drilling, if necessary, a thrombin soaked sponge may be inserted through the extended outer sleeve **140** and into the cylindrical hole **290** to coagulate any bleeding. The thrombin soaked sponge is then removed and the surgeon utilizing an endoscope then visually inspects the cylindrical hole **290** for any remaining discal material, and removes any such material requiring such removal with a surgical instrument such as a curette or rongeur.

Referring to FIG. **18**, with the extended outer sleeve **140** still in place, the surgical site is now fully prepared to receive a spinal implant I for fusion of the vertebrae T_7 and T_8. The spinal implant I may be coated with, and/or made of, and/or loaded with substances consistent with bony fusion which may promote bone growth and/or fusion prior to being implanted. Once the spinal implant I has been prepared for implantation, a driver instrument, such as driver **300** may be used to either insert or to remove spinal implant I. Driver **300** has at its distal end **302**, a rectangular protrusion **304**, which intimately engages the complimentary rectangular slot in the rear of implant I. Extending from the rectangular protrusion **304** is threaded portion **306**, which extends as a rod through hollow shaft **308** and hollow barrel portion **310** to knob **312** where it can be rotationally controlled. Threaded portion **306** screws into a threaded aperture in the spinal implant I and binding them together such that driver **300** can be rotated via paired and diametrically opposed extending arms **314** and **316** and in either direction while maintaining contact with the spinal implant I.

Affixed to the driver **300**, the spinal implant I is then introduced through the extended outer sleeve **140** and if the spinal implant I is threaded, screwed into the cylindrical hole **290** between the two vertebrae T_7 and T_8 until such time as the leading edge of the implant cap **318** reaches the depth of the cylindrical hole **290** at which time its forward motion is impeded by the bone lying before it which had not been drilled out. This allows for a progressive feel to the surgeon as the spinal implant I is inserted into place. It is appreciated that if the spinal implant I is not threaded, instead of being screwed into hole **290**, it may be linearly advanced into hole **290** by pushing the driver **300** toward the hole **290**.

The terminal resistance to further seating provides significant tactile feedback to the surgeon. Visual monitoring of the depth of insertion of the spinal implant I is provided to the surgeon by observing the progressive approximation of the forward surface **320**, of barrel portion **310**, as it approaches the rearward facing surface **172** of extended outer sleeve **140** and/or by the use of an image intensifier. As a final safety mechanism, when the full depth of insertion has been achieved, forward surface **320** of instrument **350** will abut surface **172** of the extended outer sleeve **140**, prohibiting any further installation of the implant. Once the spinal implant has been fully installed, the driver **300** is dissociated from the implant by turning knob **312** in a counterclockwise direction. The driver **300** is then withdrawn from the extended outer sleeve **140**.

Referring to FIG. **19**, the spinal implant I is shown fully installed to the determined depth in the cylindrical hole **290** drilled across the disc space D and into the adjacent vertebrae T_7 and T_8. The spinal implant I shown comprises a hollow tubular member which in the preferred embodiment is made of an ASTM surgically implantable material, preferably titanium. However, it is appreciated that other implants, cylindrical or partially cylindrical, or of a variety of shapes, and with or without threads or surface roughenings may be used with the instrumentation and method of the present invention.

Referring to FIGS. **20** and **21**, an extractor cap **340** for removing the extended outer sleeve **140** is shown about to be coupled to the extended outer sleeve **140**. The extractor cap **340** engages the proximal end **157** of the extended outer sleeve **140** by spring tabs **342***a* and **342***b* on either side of extractor cap **340** which snap-fit into openings **344***a* and **344***b* on either side of the extended outer sleeve **140** to lock in place. The extractor cap **340** has a top **346** that is similar in structure to the proximal end of the distractor **100**, having a recess portion **350** and a crown portion **352**.

Referring to FIG. **22**, once the extractor cap **340** is coupled to the extended outer sleeve **140**, the distractor puller **200** is coupled to the top **346** of extractor cap **340** to remove the extended outer sleeve **140** from the disc space D and from the adjacent vertebrae T_7 and T_8 in the direction of the arrow Z.

Referring to FIG. **23**, once the extended outer sleeve **140** has been removed, the spinal implant I remains implanted within the cylindrical hole **290** drilled across the disc space D and the implant engages the two adjacent vertebrae T_7 and T_8.

Referring to FIG. **24**, the spinal implant I may be further stabilized with use of a spinal fixation device **400** such as the staple disclosed in copending U.S. application Ser. No. 08/219,626 entitled APPARATUS, INSTRUMENTATION AND METHOD FOR SPINAL FIXATION, which is incorporated herein by reference. The spinal fixation device **400** is coupled to the spinal implant I with a locking screw **416** and engages the vertebrae T_7 and T_8 via prongs **420** and **422**. The spinal fixation device **400** functions to stabilize the spinal implant I and prevent any unwanted excursion of the spinal implant I during the spinal fusion process. It is appreciated that prior to removal of the extended outer sleeve **140**, a centering post (not shown) may be inserted through the extended outer sleeve **140** and attached to the threaded opening in the back of the spinal implant I. The extended outer

sleeve **140** is then removed and the centering post functions as guide to align the spinal fixation device **400** as it is being driven into the vertebrae T_7 and T_8 as described in detail in the copending application referenced immediately above.

In the above description in regard to the thoracic spine, the surgical procedure has been described as being performed through a hollow tube (extended outer sleeve **140**) and with the aid of a thorascope. It is appreciated that there may be circumstances where the surgeon will elect to perform the surgical procedure through an incision, such as a thoracotomy, where direct visualization of the surgical site is possible obviating the need for the thorascope but without diminishing the teaching of the method of the present invention. In such cases, a modification of the extended outer sleeve **140**, such as the extended outer sleeve **1100** shown in FIG. **35** and described in detail below, having a detachable distal end may be beneficially utilized by the surgeon. In this manner, the surgeon has direct visualization of the surgical site while the proper distraction and alignment of the adjacent vertebrae is maintained throughout the procedure by the distal end of the extended outer sleeve.

While the present invention has been described in association with the insertion of a threaded spinal implant, it is recognized that other forms of implants may be used with the present method. For example, dowels, made from bone, coral or artificial materials, knurled or irregularly shaped cylinders or spheres, partial cylinders or any other shaped implants that can be introduced through the extended outer sleeve **140**, which itself need not be cylindrical may be used.

When such implants are used, it is appreciated that the steps of the method of the present invention described above may be reduced. For example, once the extended outer sleeve **140** has been seated such that the extension portion **148** is inserted in the disc space D and the prongs **149** and **150** engage the adjacent vertebrae, the step of inserting the inner sleeve **242** may be omitted and a drill having a diameter approximating that of the inner diameter of the extended outer sleeve **140** may be used to drill a hole the size of the inner diameter of the extended outer sleeve **140** across the disc space D and into the adjacent vertebrae. Once the drill has been removed, any remaining discal material or debris may be removed by irrigating and vacuuming the hole, and an implant such as a bone dowel or an implant without threads, may be linearly advanced through the extended outer sleeve **140** and implanted into the hole. The extended outer sleeve **140** is then removed in the same manner described above. Where the implant shape is generally not circular, an appropriately shaped chisel may be used by itself or in conjunction with a drill to prepare an opening for the fusion implant that is other than round.

It is further appreciated that it is also within the scope of the present invention to provide a method and instrumentation for the insertion of a spinal implant into the disc space between two adjacent vertebrae, without the drilling away of significant bone from the vertebrae. Such implants may have a height corresponding to the height of a disc space D and may be pushed into the disc space D when distracted once the disc space has been cleaned out. This type of implant would preferably have in part a rectangular cross section and an extended outer sleeve used for the insertion of such implants would have a corresponding cross section and shape. Further, it is appreciated that the extended outer sleeve and inner sleeve of the present invention may have any shape or size corresponding to the shape and size of the implant to be inserted without departing from the scope of the present invention.

While the above description has been directed to the thoracic spine, the method and instrumentation of the present invention may also be utilized in the lumbar spine. In the preferred method, the surgeon makes a small incision in the abdominal wall and gently dissects his way retroperitoneal to reach the lateral aspect of the spine. As with the thoracopic method described above, the surgeon may use an endoscope within and/or outside of the extended outer sleeve to facilitate the surgery, and thereby require an incision barely larger than the diameter of the extended outer sleeve which itself is not much larger than the implant.

Referring to FIG. **25**, an extended outer sleeve **1000** for use with the lateral method in the lumbar spine is shown. The extended outer sleeve **1000** is similar to the extended outer sleeve **140** described above and comprises a hollow tubular member **1002** having a distal end **1010** which is contoured to hug the vertebrae, for example L_4 and L_5. The extended outer sleeve **1000** has anterior and posterior extension members **1020** and **1022**, each having different heights, that are opposed 180 degrees from each other. Also extending from the distal end **1010** may be prongs **1012** and **1014**, similar to prongs **149** and **150** described above, for engaging the bone of the adjacent vertebrae L_4 and L_5. The extension members **1020** and **1022** are tapered at their leading edges **1024** and **1026** respectively, to facilitate insertion.

As shown in FIGS. **26-28**, the extended outer sleeve **1000** is designed to be used in approaching the lumbar spine laterally from either side of the spinal column. The extended outer sleeve **1000** by means of its extended portions **1020** and **1022** is capable of correcting those spinal deformities, such as scoliosis or any abnormality of kyphosis or lordosis, occurring specifically from a deformity of the disc. For example, in order to restore lordosis in the lumbar spine, the anterior extension member **1020** is placed anteriorly between the adjacent vertebrae L_4 and L_5 and the posterior extension member **1022**, having a lesser height than the extension member **1020**, is placed posteriorly. The greater height of the extension member **1020** relative to the extension member **1022** maintains the anterior portions of the vertebrae L_4 and L_5 spaced apart at a greater distance than the posterior portions of the vertebrae L_4 and L_5 producing an angular relationship between the bodies as would exist with naturally occurring physiologic lordosis. Once restored, lordosis is maintained throughout the surgical procedure.

Scoliosis refers to an abnormal curving of the spine when viewed from straight ahead or behind. Since the extension members **1020** and **1022** may be of a specific and constant height throughout their entire lengths, both sides of the disc space D are lifted to exactly the same height, thus eliminating any side to side angular deformity occurring through that disc space.

Referring specifically to FIG. **26**, it can be appreciated that the posterior extension member **1022** effectively prevents any injury to the dural sac and neural elements, while the anterior extension member **1020** in a similar fashion, protects the great blood vessels including the aorta, vena cave and the iliac arteries and veins. As the extended outer sleeve **1000** of the present invention is quite stable once inserted, the preferred embodiment is shown as having only two prongs **1012** and **1014**, one each to engage each of the adjacent vertebrae L_4 and L_5. It is, however, understood that the extended outer sleeve **1000** may have more or less prongs or none at all. The distal end **1010** of the tubular member **1002** is contoured adjacent the origin of the anterior and posterior extended members **1020** and **1022** so as to assure an intimate fit between the tubular member **1002** and the vertebrae L_4 and L_5 adjacent the disc space D to which it is opposed, and for the purpose of confining the surgery to within the extended outer sleeve **1000** and excluding the adjacent soft tissues from

potential injury. In the preferred embodiment, the distal end of the tubular member **1002** and the anterior and posterior extended members **1020** and **1022** themselves have been reinforced, that is are thicker than the adjacent tubular member **1002** itself so as to provide for increased support within the lumbar spine.

Referring still to FIG. **26**, the extended outer sleeve **1000** engages the spine laterally, although the surgical approach in reaching the spine may be from an anterior, lateral, or anterior-lateral incision on the outside of the body, and is hereinafter referred to as the "Lateral Method". The "Lateral Method" involves the insertion of a distractor, such as, but not limited to the distractor **100** described above into the lateral aspect of the spine, and generally from a side to side direction although said direction could be slightly from anterolateral to slightly posterolateral (diagonalized from the transverse axis) without departing from the teaching of the method of the present invention to distract the adjacent vertebrae, in this example, L_4 and L_5. Once the distractor **100** is in place, if fusion alone is to be performed, then the extended outer sleeve **1000** having both anterior and posterior extension members **1020** and **1022** is utilized. The extended outer sleeve **1000** is placed over the distractor **100** such that the posterior extension member **1022** is positioned at the posterior aspect of the spine and the anterior extension member **1020** is positioned at the anterior aspect of the spine. Once the extended outer sleeve **1000** is in place, the distractor **100** is removed. Alternatively, it is appreciated that the "Lateral Method" may be performed without the use of a distractor. Instead, the extended outer sleeve **1000** may be inserted from the lateral aspect of the spine directly since the extension members **1020** and **1022** function to distract the adjacent vertebrae L_4 and L_5 to restore and maintain the normal angular relationship of those vertebrae L_4 and L_5.

If the implant to be inserted has surface irregularities such that there is a major diameter (including the surface irregularities) and a minor diameter (excluding the surface irregularities), then an inner sleeve **1040** similar to the inner sleeve **242** described above, may be inserted into the extended outer sleeve **1000**. The inner sleeve **1040** functions as a drill guide and spacer having a thickness which corresponds to the difference between the major and minor diameters of such implant as described in detail above in reference to an inner sleeve **1040**. A drill **250**, described above, is inserted into the inner sleeve **1040** and is used to drill the vertebrae with the inner sleeve **1040** providing a more intimate fit to the drill **250**, than the larger bore of the extended outer sleeve **1000** could have alone and thus more precisely controlling the path of the drill **250**. The inner sleeve **1040** and the drill **250** may be removed from the extended outer sleeve **1000** together thus trapping and removing much of the debris produced by the actual drilling. It is appreciated that in the alternative, a drill (not shown) may be used such that the distal bone engaging portion has an outside diameter generally corresponding to the minor diameter of the implant and more proximally, a shaft portion with a larger diameter generally corresponding to the major diameter of the implant. An implant I may then be inserted according to the method described above. If the implant to be inserted does not have a major and minor diameter, then no inner sleeve is required, and the drill **250** having a diameter corresponding with the diameter of such an implant may be inserted directly into extended outer sleeve to drill the vertebrae L_4 and L_5.

While not considered the preferred method under most circumstances it is nevertheless anticipated that one could drill the described hole across the disc space and into each of the adjacent vertebrae from the lateral aspect of the spine and in at least a partially side to side direction through the extended outer sleeve and then remove the extended outer sleeve and insert at least one spinal implant also from the lateral aspect of the spine and in an at least a partially side to side direction and with or without the use of some form of spinal distractor. In which circumstance the use of an inner sleeve is of less importance than that the size of the opening created is sufficient such that it is possible to insert the implant. To that end and independent of whether the extended outer sleeve is left in place for implant insertion, and whether an inner sleeve is used during drilling it is anticipated and should be appreciated that the extended outer sleeve and opening may be of a variety of shapes and that the creation of spaces of varied shapes across a disc and within the spine may be achieved by use of an instrument appropriate for the surgical removal of spinal material, such as a chisel or a router, and with or without the use of a drill, and/or an inner sleeve, and/or an extended outer sleeve; and with the essential element being that the space within the spine is being created across a disc intermediate two adjacent vertebrae from the lateral aspect of said disc and at least in part in a from side to side direction and that an implant is then inserted also from the lateral aspect of said disc which implant occupies at least in part said space, engages at least in part each of the vertebrae adjacent said disc space and comes to lie in an at least partially side to side direction across said disc space.

Referring to FIGS. **29** and **30**, the implant I and J are shown inserted across the disc spaces D between vertebrae L_3, L_4 and L_5, respectively. FIG. **30** is a top sectional view along lines **30-30** of FIG. **29** showing the area of contact of the implant I and the vertebrae L_4. It can be seen from FIG. **30** that the implant I has a true lateral orientation with respect to the vertebra L_4, such that there is a great area of contact between the implant I and the vertebra L_4.

Referring to FIG. **30**A, a top sectional view of a vertebra similar to FIG. **30** is shown illustrating the area of contact of the implant I and the vertebrae L_4 when the implant I is inserted with the "Lateral Method" of the present invention from a slightly anterior position (anterolateral) along the Lateral aspect of the spine and in an at least partially side to side direction.

Referring to FIGS. **31** and **32**, illustrating the prior art method, two implants **1050** and **1052** are inserted from the anterior or posterior aspect of the spine so that they are oriented in an anterior to posterior direction across the disc space D and vertebrae L_4 and L_5. It can be seen that implants **1050** and **1052** must have a much smaller diameter than implant I to fit within the width of the spine and therefore have very small areas of engagement to the vertebrae themselves as most of the diameter of the implants is used in just spanning across the height of the disc before contacting said vertebrae. FIG. **32** is a top sectional view along lines **32-32** of FIG. **31** showing the area of contact of the two spinal implants **1050** and **1052** and the vertebra L_5.

Referring to FIG. **33**, a top sectional view showing the area of contact of a cylindrical spinal implant **1090** having the same diameter as implant I shown in FIG. **30**, inserted from the anterior to posterior direction across the vertebra L_5 is shown and seen to have by necessity a much shorter length.

Referring to FIGS. **30** and **32-33**, it can then be appreciated that an implant I inserted from the lateral aspect of the spine may have a diameter almost as great as the depth of the spine from front to back at that location unlike two implants such as implants **1050** and **1052** inserted side by side from front to back or the reverse where each implant can have a diameter no greater than one half the width of the spine at that level. It can further be appreciated that while the height of the disc space

itself hardly affects the area of contact of the single large implant I with the adjacent vertebrae, it substantially effects the area of contact of the two implants **1050** and **1052** inserted in the front to back directions side by side. Further, as the lumbar vertebrae and discs are much wider from side to side then they are deep from front to back, it can be appreciated that when single implants of the same diameter are inserted across a given lumbar disc, the laterally inserted implant I may be of a much greater length and thus have more area of contact, for stability and fusion than implant **1090** inserted from anterior to posterior.

Referring to FIG. **34**, a segment of the spinal column having single implants **1095** and **1096** inserted from front to back at adjacent disc levels between three vertebrae V_{1-3} is shown. As it can be seen in FIG. **34**, it is generally not possible to increase the diameter of singular implants inserted from front to back without risking severe structural and vascular damage to that area of the spine. Implants **1095** and **1096** each have a diameter that is substantially greater than the diameter of implant **1090**, such that implants **1095** and **1096** could in theory have a greater area of contact with the adjacent vertebrae than it **1090**. However, in application, as a result of the larger diameter of the implants **1095** and **1096**, a large portion of bone from the adjacent vertebrae would have to be removed to accommodate the large diameter of each of the implants **1095** and **1096** which would significantly weaken the structural integrity of those vertebrae. This is especially a problem when as shown in FIG. **34**, implants **1095** and **1096** are inserted at adjacent disc levels such that the intermediate vertebrae V_2 would be cut in half to form a "butterfly" pattern resulting in the complete loss of the structural integrity of vertebrae V_2.

Thus, the implant I of the present invention inserted laterally provides for greater surface area of contact, the largest volume of fusion promoting material, and the greatest mechanical engagement and thus stability, and is therefore an improvement upon other methods of implant insertion in facilitating a successful fusion.

Referring to FIG. **35**, an alternative embodiment of the extended outer sleeve is shown and generally referred to by the numeral **1100**. As only a single relatively small incision (approximately three inches or less) is required through the abdominal wall of the patient to perform the procedure for the fusion of two vertebrae adjacent a disc space in the lumbar spine, it is anticipated that the surgeon may prefer to perform the method of the present invention under direct vision, without the need for an endoscope. In such a circumstance, a convertible extended outer sleeve **1100** may be used. The convertible extended outer sleeve **1100** may be similar in structure to the extended outer sleeve **1000**, except that it comprises a hollow tubular member **1102** that is disengageable from the distal end portion **1104** of the convertible extended outer sleeve **1100**. As shown in FIG. **35** the extended outer sleeve **1100** has a detachable hollow tubular member **1102**. The vertebrae engaging distal end portion **1104** may be as shown in FIG. **35** or may be similar to the distal end shown previously in FIG. **7**A, such that the convertible extended outer sleeve **1100** may be useable throughout the spine.

The convertible extended outer sleeve **1100** is inserted in the disc space D and the adjacent vertebrae L_4 and L_5 as described above for the extended outer sleeve **1000**. Once the extension member **1120** is seated in the disc space D and the prongs **1112** and **1114** are engaged to the vertebrae L_4 and L_5, the hollow tubular member **1102** may be dissociated from the distal end portion **1104** which remains engaged to the vertebrae L_4 and L_5. In this manner, if an incision is made to access the spine directly, the surgeon may access the disc space D through the distal end portion **1104** which is closer to the spine, without having to pass through the entire length of the convertible extended outer sleeve **1100**. With the distal end portion **1104** in place, the vertebrae remain distracted and aligned, and since the hollow tubular member **1102** has been removed, it is then possible for the surgeon to work in and around the spine under direct vision. The shortened distal end portion **1104** of the convertible extended outer sleeve **1100** left protruding from the adjacent vertebrae may be selected to be of a length such that it still serves to offer some protection to the large blood vessels which are safely positioned outside of the remaining working channel. Alternatively it can be of any length so as to fulfill the surgeon's purposes. The hollow tubular member **1102** may be re-engaged to the distal end portion **1104** for inserting an implant I in the manner described above.

In the specific embodiment of the convertible extended outer sleeve **1100**, the distal end portion **1104** has a single extension member **1120** and two prongs **1112** and **1114** positioned approximately 120 degrees from the extension member **1120** for engaging the two adjacent vertebrae L_4 and L_5, for the purpose of allowing the surgeon direct access to the spinal canal. Thus, if a discectomy is to be performed, an extended outer sleeve having a single anterior intradiscal extended member **1120**, but without a posterior extended member, and with two vertebrae engaging prongs **1112** and **1114** may be used.

It is appreciated that for surgery on the thoracic spine, while the method described above wherein the entire procedure is performed through the extended outer sleeve **140** is preferred, it is also possible to utilize the convertible extended outer sleeve **1100** when a full thoracotomy is made to access the thoracic spine without having to work through the entire length of the extended outer sleeve, in this manner the surgeon may directly visualize and access the surgical site.

Further, combining the features of the absence of any posterior intradiscal extended member with the convertible extended outer sleeve **1100** permits easy and direct access to the spinal canal for removal of any diseased discal material.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention.

I claim:

1. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

positioning said third surgical instrument such that said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies of the two adjacent vertebrae; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, a non-bone interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

2. The method of claim **1**, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

3. The method of claim **2**, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

4. The method of claim **1**, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

5. The method of claim **4**, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

6. The method of claim **4**, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

7. The method of claim **1**, further comprising coupling a spinal fixation device to said implant and engaging said spinal fixation device to the adjacent vertebrae.

8. The method of claim **1**, wherein said fusion implant is provided in combination with fusion promoting substances.

9. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

positioning a single elongated portion removably attached to said distal end of said third surgical instrument over the disc space, said single elongated portion having a length, a thickness, and a width, the length of said single elongated portion being greater than the width and the thickness of said single elongated portion, the width of said single elongated portion being greater than the thickness of said single elongated portion, said single elongated portion being tapered to facilitate entry between the vertebral bodies of the two adjacent vertebrae;

inserting said single elongated portion into the disc space with the width of said single elongated portion being oriented along a height of the disc space; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

10. The method of claim **9**, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

11. The method of claim 10, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

12. The method of claim 9, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

13. The method of claim 12, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

14. The method of claim 12, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

15. The method of claim 9, further comprising coupling a spinal fixation device to said implant and engaging said spinal fixation device to the adjacent vertebrae.

16. The method of claim 9, wherein said fusion implant is provided in combination with fusion promoting substances.

17. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end, said third surgical instrument having at least two elongated portions for insertion into the patient, each of said elongated portions having a length, a width, and a thickness, said length of each of said at least two elongated portions being greater than the width and the thickness of said at least two elongated portions, each of said at least two elongated portions have a cross section through the width and the thickness and perpendicular to the length of said at least two elongated portions, respectively, each cross section of said at least two elongated portions having a convex exterior surface, said convex surfaces of each of said at least two elongated portions having the same curvature;

positioning said third surgical instrument such that at least part of one of said at least two elongated portions is over one of the two adjacent vertebrae and at least part of another of said at least two elongated portions is over the other of the two adjacent vertebrae; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

18. The method of claim 17, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

19. The method of claim 18, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

20. The method of claim 17, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

21. The method of claim 20, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

22. The method of claim 20, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

23. The method of claim 17, wherein said fusion implant is provided in combination with fusion promoting substances.

24. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision and along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of said length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length there between, said sec-

ond surgical instrument having a passageway configured to receive a portion of said length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end, said third surgical instrument having a first, a second, and a third elongated portion for insertion into the patient, each of said elongated portions having a length, a width, and a thickness, the length of said first elongated portion being greater than the width and the thickness of said first elongated portion, the width of said first elongated portion being greater than the thickness of said first elongated portion, the width of said first elongated portion proximate said distal end of said third surgical instrument having a midpoint, the length of said second elongated portion being greater than the width and the thickness of said second elongated portion, the length of said third elongated portion being greater than the width and the thickness of said third elongated portion, each of said first, second, and third elongated portions have a cross section through the width and the thickness and perpendicular to the length thereof, each cross section of said first, second, and third elongated portions having a convex exterior surface, said convex exterior surfaces of each of said second and third elongated portions having the same curvature;

positioning said third surgical instrument such that the midpoint of the width of said first elongated portion is over the disc space and said second elongated portion is over one of the two adjacent vertebrae and said third elongated portion is over the other of the two adjacent vertebrae;

withdrawing said second surgical instrument and said first surgical instrument from the body; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

25. The method of claim **24** further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

26. The method of claim **25** wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

27. The method of claim **24** further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

28. The method of claim **27** wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

29. The method of claim **27** wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

30. The method of claim **24** wherein said fusion implant is provided in combination with fusion promoting substances.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,251,997 B2
APPLICATION NO. : 13/306583
DATED : August 28, 2012
INVENTOR(S) : Gary Karlin Michelson

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page 1, Item (56) References Cited, U.S. Patent Documents:
Column 2, line 3, change "Moreira" to -- De G. Moreira --.

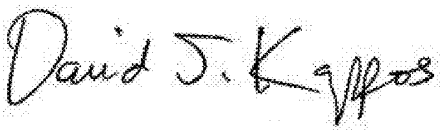
Title Page 3, Item (56) References Cited, Foreign Patent Documents:
Column 1, line 64, change "6/1982" to -- 6/1986 --.

Title Page 3, Item (56) References Cited, Other Publications:
Column 2, line 20, change "12/655/178" to -- 12/655,178 --;
Column 2, line 23, change "on Bone" to -- of Bone --;
Column 2, line 41, change "Sincipitai" to -- Sincipital --; and
Column 2, line 65, change "61.793-794" to -- 61:793-794 --.

Title Page 4, Item (56) References Cited, Other Publications:
Column 1, line 6, change "Transiation" to -- Transition --;
Column 1, line 37, change "Alloplastic, Materials" to -- Alloplastic Materials --;
Column 1, line 59, change "Medics" to -- Medica --;
Column 1, line 65, change "Paul M," to -- Paul M. --;
Column 1, line 66, change "114-.122" to -- 114-122 --;
Column 2, line 4, change "et al.:" to -- et al.; --;
Column 2, line 6, change "3-20)," to -- 3-20, --;
Column 2, line 20, change "Retropedtoneal" to -- Retroperitoneal --;
Column 2, line 22, change "5,7" to -- 5.7 --;
Column 2, line 25, change "1998,." to -- 1998. --;
Column 2, line 35, change "45:628-6387" to -- 45:628-637 --;
Column 2, line 53, change "Willberger" to -- Wiltberger --; and
Column 2, line 56, change "Acronex" to -- AcroFlex --.

Title Page 5, Item (56) References Cited, Other Publications:
Column 1, line 36, change "et al.'s l" to -- et al.'s --;

Signed and Sealed this
Eighth Day of January, 2013



David J. Kappos
Director of the United States Patent and Trademark Office

CERTIFICATE OF CORRECTION (continued)
U.S. Pat. No. 8,251,997 B2

Column 1, line 69, change "6,946,933" to -- 6,945,933 --;
Column 2, line 10, change "08cv1 512-" to -- 08cv1512- --;
Column 2, line 21, change "B,10," to -- B.10, --;
Column 2, line 25, change "8.22," to -- B.22, --;
Column 2, line 28, change "M.D.." to -- M.D., --;
Column 2, line 32, change "M,B,A.," to -- M.B.A., --;
Column 2, line 36, change "iInc.'s" to -- Inc.s --;
Column 2, line 53, change "pages" to -- pages; --; and
Column 2, line 66, change "Sep. 20" to -- Sep. 29 --.

Title Page 6, Item (56) References Cited, Other Publications:
Column 1, line 56, change "Bono" to -- Bone --;
Column 1, line 64, change "Thoracotorny" to -- Thoracotomy --;
Column 2, line 13, change "Acrorned" to -- Acromed --;
Column 2, line 15, change "*Spione*" to -- *Spine* --; and
Column 2, line 26, change "Structrual" to -- Structural --.

Title Page 7, Item (56) References Cited, Other Publications:
Column 1, line 9, change "inc.'s" to -- Inc.'s --;
Column 1, line 13, change "Worksheet;" to -- Worksheet, --;
Column 2, line 5, change "Nuvasive." to -- Nuvasive, --;
Column 2, line 8, change "7;470;236" to -- 7,470,236 --;
Column 2, line 11, change "Sofarnor" to -- Sofamor --;
Column 2, line 13, change "at al." to -- et al. --; and
Column 2, line 14, after "Disclosure" insert -- of Asserted --.

CERTIFICATE OF SERVICE

On May 29, 2015, this brief was submitted to the Court through the CM/ECF system. All parties are represented by CM/ECF users and will be served by the CM/ECF system.

/s/ John C. O'Quinn

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 28.1(e)(2). According to the word processing system used to prepare it, the brief contains 16,391 words.

/s/ John C. O'Quinn

U.S. Patent No. 8,251,997 B2, Claim 24 (A114-15):

24. A method comprising: making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision and along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of said length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length there between, said second surgical instrument having a passageway configured to receive a portion of said length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end, said third surgical instrument having a first, a second, and a third elongated portion for insertion into the patient, each of said elongated portions having a length, a width, and a thickness, the length of said first elongated portion being greater than the width and the thickness of said first elongated portion, the width of said first elongated portion being greater than the thickness of said first elongated portion, the width of said first elongated portion proximate said distal end of said third surgical instrument having a midpoint, the length of said second elongated portion being greater than the width and the thickness of said second elongated portion, the length of said third elongated portion being greater than the width and the thickness of said third elongated portion, each of said first, second, and third elongated portions have a cross section through the width and the thickness and perpendicular to the length thereof, each cross section of said first, second, and third elongated portions having a convex exterior surface, said convex exterior surfaces of each of said second and third elongated portions having the same curvature;

positioning said third surgical instrument such that the midpoint of the width of said first elongated portion is over the disc space and said second elongated portion is over one of the two adjacent vertebrae and said third elongated portion is over the other of the two adjacent vertebrae;

withdrawing said second surgical instrument and said first surgical instrument from the body;

and inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.